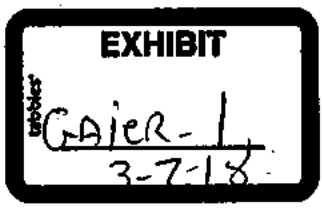
Exhibit 68



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA et al., ex rel. OSWALD BILOTTA v. NOVARTIS PHARMACEUTICALS CORPORATION	Case No. 11 Civ. 0071 (PGG)

EXPERT REPORT OF ERIC M. GAIER, PHD

December 11, 2017

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I. Introduction

I.A. Qualifications

(1) I am a Partner and founding member of Bates White Economic Consulting (Bates White), a professional services firm that conducts economic and statistical analyses in a variety of industries and forums. I am currently the coleader of Bates White's Healthcare and Life Sciences Practice, and I specialize in performing economic and statistical analyses in connection with antitrust, fraud, false claims, Anti-Kickback Statute (AKS), and other litigation and regulatory matters. Before joining Bates White, I was an Associate with the management consulting firm of A.T. Kearney and a Research Fellow with the Logistics Management Institute, a federally funded research and development center. Previously, I served as a Consultant to the National Research Council and as an Instructor in the Department of Economics at Duke University.

(2) I received my PhD in Economics from Duke University in 1997 and my BA in Economics from Florida State University in 1992. My doctoral fields of concentration included economic theory, industrial organization, and econometrics. While at Duke University, I taught numerous courses, including Introductory Microeconomics (undergraduate level), Intermediate Microeconomics (graduate and undergraduate levels), and Introductory Macroeconomics (undergraduate level). In my doctoral dissertation, I analyzed the effect of information on competition and pricing, as well as the incentives of buyers and sellers in a variety of markets and contexts. I have published economic articles in peer-reviewed journals, written a chapter in a peer-reviewed National Academy of Sciences book, and authored numerous economic reports for the National Aeronautics and Space Administration (NASA).

(3) I have been retained as a consultant or expert witness in connection with matters of alleged fraud, deception, false claims, or competition policy in a variety of industries. During the past decade, I have focused primarily on matters in the healthcare and life sciences industries, including numerous matters concerning government and private health insurance; pharmaceutical pricing, distribution, and reimbursement; and medical devices. I have provided deposition, hearing, and trial testimony in numerous matters and have previously been qualified by courts as an expert economist; a healthcare economist; and an expert in economic loss, pharmaceutical economics, and data analysis.

(4) Healthcare economics refers to the application of economic theory and empirical methods to research topics relevant to the healthcare industry. In my work as a healthcare economist, I have applied both economic theory and empirical methods to a variety of healthcare topics, including questions related to the adequacy of reimbursements provided by private and government health insurance programs,

incentives of pharmaceutical manufacturers to develop novel drugs, and effects of alleged off-label marketing and alleged inducements on prescribing patterns. Much of my expert work in healthcare and life sciences matters has involved empirical analysis of sales, prescriptions, and reimbursement data pertaining to a variety of products and services provided by manufacturers and healthcare professionals. For example, in *United States v. Guidant Corp.*, I analyzed Medicare claims data in connection with alleged False Claims Act (FCA) violations concerning alleged off-label marketing of certain implantable cardiac devices manufactured and distributed by Guidant. In *United States v. Novartis Pharmaceuticals Corp.*, I analyzed Medicare and Medicaid claims data in connection with alleged FCA violations associated with alleged kickbacks concerning Novartis's distribution of two specialty brand-name pharmaceuticals: Myfortic and Exjade. In *In re Pharmaceutical Industry Average Wholesale Price Litigation*, I analyzed prescription drug claims data provided by numerous private insurers in connection with allegations of deceptive pricing practices. In addition, I analyzed state Medicaid prescription drug claims data in connection with numerous state litigations concerning Average Wholesale Price (AWP) pricing practices.

(5) A copy of my curriculum vitae is attached as Appendix A. Bates White is being compensated for my time in this matter at a rate of $675 per hour. Additional Bates White staff billed time for supporting me at rates ranging from $230 to $675 per hour. None of Bates White's compensation is contingent upon the outcome of this litigation.

I.B. Summary of allegations

(6) This matter concerns alleged FCA violations due to alleged AKS violations associated with ten brand-name self-administered prescription drugs manufactured and marketed by Novartis Pharmaceuticals Corporation (Novartis).[1] According to the Amended Complaint in Intervention of the United States of America (Complaint), the government alleges that:

> [F]rom January 2002 through at least November 2011, Novartis systematically paid doctors to speak about certain of its drugs, including its cardiovascular drugs Lotrel and Valturna and its diabetes drug Starlix, at events that were often little or nothing more than social occasions for the doctors. The payments to the doctors, and the dinners, were kickbacks to the speakers and the attendees to induce them to write prescriptions for Novartis drugs.[2]

[1] Nine subject drugs are indicated to treat hypertension and one is indicated to treat type 2 diabetes. The subject antihypertension drugs in alphabetical order are Diovan, Diovan HCT, Exforge, Exforge HCT, Lotrel, Tekamlo, Tekturna, Tekturna HCT, and Valturna. The subject type 2 diabetes drug is Starlix. I describe each of these subject drugs in section IV.A. Amended Complaint in Intervention of the United States, Aug. 26, 2013 [hereinafter Complaint], ¶¶ 68–69.

[2] Complaint, ¶ 1.

(7) I understand that several of the subject drugs were covered by a prior settlement agreement between Novartis and the government that limits the time period at issue for promotion and prescriptions of those drugs in this matter. Specifically, I understand that Novartis contends that Diovan, Exforge, and Tekturna events and prescriptions prior to January 1, 2010 are not at-issue in this matter. Furthermore, I understand that Novartis contends that the prior settlement agreement also covers Diovan HCT, Exforge HCT, and Tekturna HCT events and prescriptions prior to January 1, 2010.

(8) Through its experts, the government has identified 56,641 healthcare providers that the government alleges were provided kickbacks by Novartis for at least one of three reasons, as follows:[3]

- "Repeat Attendance," defined by Dr. Goldberg as:

  > Any event attended by a doctor after he or she attended two or more events for the same specified drug when considering Speaker Programs (including PILS) and Roundtables in the prior 182 days.[4]

- "Speaker then Attendee," defined by Dr. Goldberg as:

  > Any Speaker Programs (including PILS) attended by a doctor after the doctor had previously been a speaker at a Speaker Program for the same specified drug in the prior 182 days.[5]

- "Repeated Excessive Meal Spend," defined by Dr. Goldberg as:

  > Any Speaker Programs (including PILS) or Roundtable at which a doctor participated with a per-person spending on meals of $125 or more if the doctor had participated in at least two other such events, for any of the drugs at issue, with a per person meal spend of $125 or more in the prior 364 days.[6]

(9) Among the three stated reasons for alleging a kickback, Repeat Attendance is by far the most frequently cited by the government's experts. For example, 55,367 (or 98%) of the 56,641 healthcare providers who met one of the three criteria, met the Repeat Attendance criteria.[7] In contrast, only 8,782 (16%) healthcare professionals met the Speaker then Attendee criteria and only 9,818 (17%) healthcare professionals met the Repeated Excessive Meal Spend criteria.[8] Hence, the primary driver

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3 Expert Report of Richard E. Goldberg, PhD, Aug. 14, 2017, [herein after Goldberg Report], p. 23.

4 Goldberg Report, p. 19.

5 Goldberg Report, p. 20.

6 Goldberg Report, p. 20.

7 *See* Goldberg Report, Table 4.

8 *See* Goldberg Report, Table 4.

of alleged damages is the government's allegations that repeated attendance at Novartis's speaker and roundtable programs constitutes a kickback.

I.C. Scope of charge and materials considered

(10) I have been retained by counsel for Novartis to provide relevant industry background information and analyze, from the perspective of healthcare economics, certain aspects of the government's allegations. For example, counsel have asked me to explain the economics of pharmaceutical promotion and analyze whether Novartis's challenged conduct was consistent with those principles. Counsel have also asked me to evaluate the opinions, analyses, and expert reports of Plaintiffs' economic experts, Prof. Daniel McFadden and Dr. Richard E. Goldberg. Counsel also asked me to review the expert reports of Plaintiff's medical experts, Drs. Graham T. McMahon and Stanley J. Schneller, which generally concern whether the challenged Novartis events would have provided educational benefits for attendees.

(11) In reaching my opinions in this matter, I considered a variety of publicly available materials, as well as nonpublic materials made available to me through counsel. A complete list of the materials that I considered is provided in Appendix B. The materials I considered in forming my opinions contain facts and data that experts in my field (i.e., economists) would reasonably rely on in forming an opinion on the subject matter of this report.

(12) I reserve the right to update my opinions if new materials become available during the course of this litigation. If I am called upon to testify at trial, I also reserve the right to employ demonstrative exhibits that summarize facts or opinions that are disclosed in this report or new information that subsequently becomes available.

II. Summary of Prof. McFadden's opinions

(13) Prof. McFadden was retained by the government to analyze "whether and to what extent Novartis prescription rates among doctors have been influenced by receiving kickbacks…through Novartis events involving ten drugs…"[9] In addition, Prof. McFadden was "asked to calculate damages to the United States and state governments for costs incurred by four health care programs (Medicare Part D, Medicaid, TRICARE, and the Veterans Administration Health Care)."[10]

(14) Prof. McFadden offers three primary opinions, as follows:

- "The kickbacks identified by the criteria caused doctors to write more prescriptions for Novartis drugs at issue than they otherwise would have."[11]
- "Between 2004 and 2011, and based on the data currently available to me, doctors who met one or more of the kickback criteria wrote 7.5 million prescriptions for which claims were submitted to and reimbursed by Medicare Part D, Medicaid, and TRICARE for Novartis's Covered Drugs while influenced by receipt of a kickback from Novartis. Based on the government's costs provided to me for payments made by Medicare Part D, Medicaid, and TRICARE, the United States paid $411 million in total and certain state governments paid $25.5 million in total for these prescriptions."[12]
- "These costs could be conservative for several reasons that are described in detail in the body of my report. These reasons include incomplete data to identify kickbacks prior to 2004 and potential undercounting of kickbacks between 2004 and 2011. The costs reported above also don't include penalties (which I understand to be available under the relevant law and am prepared to calculate), and are not trebled (which I also understand to be appropriate under the relevant law and am prepared to calculate)."[13]

(15) Prof. McFadden bases these primary opinions on the results of a regression model in which he purports to measure a relationship between new prescriptions of Novartis's subject drugs and alleged kickbacks as identified by Dr. Goldberg.[14] Specifically, based upon his model, Prof. McFadden asserts that the alleged kickbacks influenced new prescriptions in the aggregate for nine of the ten subject Novartis drugs (but not for Tekamlo) and for certain doctors during certain time periods for

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9 Expert Report of Professor Daniel McFadden on Behalf of Plaintiffs, Aug. 14, 2017 [hereinafter McFadden Report], ¶ 8.

10 McFadden Report, ¶ 8. Prof. McFadden does not calculate damages for the Veterans Administration.

11 McFadden Report, ¶ 12.

12 McFadden Report, ¶ 12.

13 McFadden Report, ¶ 12.

14 McFadden Report, ¶ 23.

those nine drugs.[15] Prof. McFadden also concludes that the alleged kickbacks did not influence aggregate prescriptions for Lotrel after entry of a generic equivalent in May 2007.[16]

(16) Prof. McFadden also asserts that his model "serves to identify whether and, if so, when kickbacks increased prescription rates by doctor, drug, and month."[17] In other words, in addition to purportedly testing aggregate influence, Prof. McFadden asserts that his model identifies influence at a doctor, drug, and month level of detail. This assertion is critical to Prof. McFadden's approach to damages, which he explains as follows:

> I was instructed to calculate damages based on the total number of prescriptions written by a given doctor during the period when my modeling reflects was [sic] that a doctor was influenced by kickbacks. The shifted Poisson model in Equation 1 identifies the months when a doctor was influenced by kickbacks.[18]

Based upon his model, Prof. McFadden concludes that "95 percent of doctors who received kickbacks and were matched to the IMS data would have prescribed fewer new prescriptions but for kickbacks."[19] In other words, Prof. McFadden concludes that 95% of the doctors flagged by Dr. Goldberg prescribed more of Novartis's subject drugs than they otherwise would have absent the alleged kickbacks.

(17) Prof. McFadden then tabulates all new prescriptions (and subsequent refills) of Novartis's subject drugs (except Tekamlo and Lotrel after May 2007) reimbursed by Medicare Part D, Medicaid, and TRICARE programs and written by doctors during time periods in which Prof. McFadden asserts that they were influenced by alleged kickbacks. Prof. McFadden concludes that approximately 7.5 million such prescriptions were subject to damages with a total cost to the United States and certain state governments of approximately $436.6 million.[20] For Medicare Part D, which is administered by private third-party payors, Prof. McFadden relies on government impact data provided by Health Integrity, a private contractor for Centers for Medicare and Medicaid Services (CMS).[21] However, in the case of managed Medicaid, Prof. McFadden simply assumes that all impact was borne by the government.

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15 McFadden Report, ¶¶ 54-55, 59.

16 McFadden Report, ¶ 55.

17 McFadden Report, ¶ 23.

18 McFadden Report, ¶ 57.

19 McFadden Report, ¶ 59.

20 McFadden Report, Table 7.

21 McFadden Report, Appendix H. Prof. McFadden also refers to the Medicare Part D government impact data as Medicare Drug Integrity Contractor (MEDIC) data. I understand that the government recently provided additional documentation for the MEDIC data. I reserve the right to supplement my opinions based upon my ongoing review of those materials and any additional information the government may provide.

(18) On September 22, 2017, the government disclosed a Supplemental Expert Report, in which Prof. McFadden applies a new methodology to extend his Medicaid damages calculations to certain states that he had previously omitted because of data limitations. Prof. McFadden relies on the same model from his initial report, but identifies additional Medicaid prescriptions that he asserts are subject to damages.

(19) On October 20, 2017, the government provided additional supplemental materials in which Prof. McFadden further revises the methodology he employed in his Supplemental Expert Report to identify additional Medicaid prescriptions. Based upon the revisions to his methodology, Prof. McFadden identifies an additional 1.0 million Medicaid prescriptions (relative to his original Expert Report) that he finds are subject to damages with a cost of $46.9 million to the U.S. Government and $30.1 million to state governments. Hence, as of his October 20, 2017 supplemental materials, the total prescriptions Prof. McFadden asserts were subject to damages increased from 7.5 million to 8.5 million and the total damages Prof. McFadden tabulates increased from $436.6 million to $513.6 million.

(20) In his initial report, Prof. McFadden provides a calculation of damages excluding events associated with pre-2010 settlement drugs. For this calculation, Prof. McFadden excludes pre-2010 events for Diovan, Exforge, and Tekturna in implementing his model, but does not exclude pre-2010 events for Diovan HCT, Exforge HCT, or Tekturna HCT.[22] After excluding pre-2010 events for Diovan, Exforge, and Tekturna, Prof. McFadden concludes that approximately 3.3 million prescriptions are subject to damages with a total cost to the United States and certain state governments of approximately $194.0 million.[23] In his supplemental materials, Prof. McFadden does not provide a corresponding sensitivity for his expanded Medicaid methodology. However, it is straightforward to extend Prof. McFadden's pre-2010 scenario to his expanded Medicaid methodology. Doing so, I conclude that Prof. McFadden would identify 3.7 million prescriptions that are purportedly subject to damages with a total cost to the United States and state governments of approximately $228.3 million.

(21) In his initial report, Prof. McFadden also provides an estimate of the incremental Novartis prescriptions he asserts were caused by the alleged kickbacks and reimbursed by government programs. That is, in contrast to his baseline damages—where Prof. McFadden counts all 7.5 million prescriptions written by doctors during time periods in which he asserts they were influenced by alleged kickbacks—Prof. McFadden finds that the alleged kickbacks caused about 330,000 incremental government-reimbursed prescriptions with a total cost to the government of $18.7 million.[24] In his supplemental materials, Prof. McFadden does not provide a corresponding figure for

[22] McFadden Report, Appendix F Table 1.

[23] McFadden Report, Appendix F Table 2.

[24] McFadden Report, Appendix G Table 1. Prof. McFadden concludes that approximately 750,000 incremental prescriptions were caused by Novartis's challenged conduct, but only about 330,000 were reimbursed by government programs. *See also* McFadden Report, Table 6.

his expanded Medicaid methodology. However, it is straightforward to extend Prof. McFadden's incremental calculations to his expanded Medicaid methodology. Doing so, I conclude that Prof. McFadden would identify about 381,000 incremental government-reimbursed prescriptions with a total cost to the government of $22.5 million. Notably, the purported 381,000 incremental prescriptions represent only 4.4% of the 8.5 million total government-reimbursed prescriptions written by doctors during time periods where Prof. McFadden asserts that they were influenced by the alleged kickbacks.

(22) In his initial report, Prof. McFadden also provides an estimate of the incremental prescriptions he asserts were caused by the alleged kickbacks, excluding pre-2010 events for Diovan, Exforge, and Tekturna (but not Diovan HCT, Exforge HCT, and Tekturna HCT). In this scenario, Prof. McFadden concludes that the alleged kickbacks caused about 85,000 incremental prescriptions with a total cost to the government of $5.0 million.[25] In his supplemental materials, Prof. McFadden does not provide a corresponding figure for his expanded Medicaid methodology. However, it is straightforward to extend Prof. McFadden's pre-2010 incremental calculations to his expanded Medicaid methodology. Doing so, I conclude that Prof. McFadden would identify about 99,000 incremental government-reimbursed prescriptions with a total cost to the government of $6.1 million. Figure 1 below summarizes Prof. McFadden's damages calculations, including those based upon his expanded Medicaid methodology.

Figure 1: Prof. McFadden's damages calculations

Treatment of events for released drugs	Total prescriptions subject to damages (thousands)	Total gov't costs (millions)	Incremental prescriptions (thousands)	Incremental gov't costs (millions)
Baseline	8,547.4	$513.6	380.6	$22.5
Exclude Diovan, Exforge, & Tekturna events prior to 2010	3,705.7	$228.3	99.2	$6.1

Source: Concerto event data; Government claims data; IMS Health; McFadden Report; McFadden supplemental materials.

(23) In his "Background" section, Prof. McFadden asserts that Novartis has maintained what he considers to be an unexpectedly high share of antihypertension drugs, at least through 2011, in the face of increasing competition from generic manufacturers. Prof. McFadden asserts that Novartis was able to maintain its purportedly high share, in part, through marketing programs.[26] Specifically, Prof. McFadden asserts:

> The data reflects that Novartis, unlike its brand name competitors, made a successful effort to maintain its market share in the face of this competition. According to

[25] McFadden Report, Appendix G Table 5.

[26] In Appendix C, I explain why this assertion is erroneous.

> Novartis's 2002 20-F report to the Security and Exchange Commission, the company responded to the competition from generics using several strategies including "marketing efforts to increase brand awareness and loyalty toward our products."[27]

(24) Finally, for each subject drug, Prof. McFadden also provides figures (and a table) purporting to illustrate the average number of new prescriptions per month written by three different groups of doctors: (1) doctors who did not participate in Novartis's events, (2) doctors who participated in Novartis's events, but did not receive alleged kickbacks, and (3) doctors who received at least one alleged kickback.[28] Based upon these figures, Prof. McFadden concludes:

> The figures demonstrate that – across these various scenarios – doctors who met the kickback criteria consistently prescribed more of the subject drugs on average than doctors who did not.[29]

[27] McFadden Report, ¶ 17.

[28] McFadden Report, ¶¶ 34–36, Table 5, Figures 4–6, Appendix D.1 Figures 1–20.

[29] McFadden Report, ¶ 36. In Appendix D, I explain why this conclusion is erroneous.

III. Summary of opinions

(25) As I explained in section I.B, the primary driver of alleged damages is the government's allegation that repeated attendance at Novartis's speaker and roundtable events constitutes a kickback. Through its medical expert, Dr. McMahon, the government alleges that healthcare providers "would obtain no educational benefit from attending three or more" events for the same drug within a six-month period.[30] According to the government's theory, if a provider received no educational benefit, then the purpose of having that provider attend the event must have been to provide a kickback.

(26) Regardless of whether any particular event lacked educational benefit for a given attendee, the government's kickback theory is based upon a false dichotomy that ignores a credible alternative purpose, at least as a matter of economics, for hosting doctors repeatedly at events: promotion.[31] Consequently, it does not follow that repeated attendance of roundtable and speaker events was necessarily a kickback to healthcare providers.

(27) Since at least the 1960s, economists have recognized that marketing serves at least two primary purposes: dissemination of information (i.e., product education) and promotion (e.g., recall, reminders, brand loyalty, etc.).[32] Importantly, marketing does not need to be strictly educational (as defined by Drs. McMahon and Schneller) in order to be effective in influencing decisions. For example, detailing, a non-challenged form of promotion that contains little formal educational content in many instances, is ubiquitous within the pharmaceutical industry and known to be highly effective in influencing prescribing.[33]

(28) Successful marketing also typically requires significant repetition, both because the uptake of messages improves with additional exposure and because the impact of messages decays in the absence of additional exposure.[34] Repetition of promotional messages is evident in Novartis's promotional data. For example, nearly 65% of healthcare professionals that attended a Lotrel event also received a Lotrel detailing visit at least every other week on average. However, the marginal impact of marketing messages typically declines with repeated exposure, a concept referred to in the

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30 Expert Report of Graham T. McMahon, M.D., M.M.Sc., Aug. 14, 2017 [hereinafter McMahon Report], ¶ 16; *see also* Expert Report of Stanley J. Schneller, M.D., Aug. 3, 2017 [hereinafter Schneller Report], p. 2.

31 Dr. Schneller appears to agree with this characterization of the events. Specifically, he states "[t]he presentations are characterized by their simplicity and repetitiveness. These features, as well as the framing of the issues, the focus on a single product, the emphasis on the benefits of a Novartis drug, the duplication of presented information, and the striking simplicity of the clinical cases presented are all characteristic of pharmaceutical promotion rather than medical education." Schneller Report, p. 22. *See also* Schneller Report, pp. 24–25.

32 Kyle Bagwell, "The Economic Analysis of Advertising," Columbia University Department of Economics Discussion Paper Series, No. 0506-01, (Aug. 2005), pp. 3–4.

33 Sridhar Narayanan and Puneet Manchanda, "Heterogeneous Learning and the Targeting of Marketing Communication for New Products," Marketing Science: Vol. 28, No. 3 (2009), pp. 425, 432.

34 *See* Marc Nerlove and Kenneth Arrow, "Optimal Advertising Policy under Dynamic Conditions;" Economica, Vol. 29, No. 114 (May 1962), pp. 129–42. Nerlove and Arrow is considered the seminal paper in economics applying the concepts of depreciation to the effectiveness of marketing.

marketing literature as "wear out."[35] Indeed, when I separate the impact of attending each subsequent event in Prof. McFadden's model, the impact for the third and subsequent repeat attendances within six months (the events that allegedly constitute kickbacks) is extremely small and significantly less than the impact his model would measure for the first and second attendances. Hence, the overall pattern of diminishing (but non-zero) marginal impacts for repeated attendance is consistent with promotional wear out.

(29) Prof. McFadden's assertion that his model "serves to identify whether and, if so, when kickbacks increased prescription rates by doctor, drug, and month" is a gross mischaracterization.[36] Prof. McFadden's model does nothing to test whether any particular doctor was influenced by alleged kickbacks. To the contrary, Prof. McFadden imposes the same impact coefficients on all doctor-month observations flagged for alleged kickbacks. In other words, Prof. McFadden's model imposes an assumption that all flagged doctor-month observations were influenced in exactly the same way for a given drug and pattern of alleged kickbacks; he does not analyze the influence of alleged kickbacks based on changes in an individual doctor's prescribing patterns. Indeed, for the high-volume subject drugs—including Diovan, Diovan HCT, Exforge, Lotrel, and Tekturna—Prof. McFadden concludes that every flagged doctor-month observation with prescribing was influenced by alleged kickbacks.[37] This is a wholly unreasonable result that demonstrates that Prof. McFadden is not testing for influence of alleged kickbacks at the doctor or doctor-month level.

(30) When I re-estimate Prof. McFadden's model (using the same data) but allow the impact of the alleged kickbacks to vary across doctors, I find that the estimated impact of the alleged kickbacks is either negative or not statistically significant for approximately 57% of flagged doctors.[38] For those doctors, there is no evidence that alleged kickbacks caused them to increase their prescribing of subject drugs, and prescriptions written by those doctors should be excluded from damages. Doing so reduces Prof. McFadden's damages calculations from $513.6 million to $283.1 million. However, as I explain below, even this remaining amount is not a reliable measure of damages because the distribution of

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35 Margaret H. Blair, "An Empirical Investigation of Advertising Wearin and Wearout," Journal of Advertising Research, Vol. 40, Issue 6, November/December 2010, pp. 95-100. *See also* Gerard J. Tellis, "Generalizations about Advertising Effectiveness in Markets." Journal of Advertising Research, Journal of Advertising Research, June 2009, *available at* www.journalofadvertisingresearch.com/content/49/2/240.

36 McFadden Report, ¶ 23.

37 For Exforge HCT, Starlix, Tekturna HCT, and Valturna, Prof. McFadden also concludes that some flagged doctor-month observations were not influenced by alleged kickbacks because those doctors only prescribed subject drugs in months with net negative impact coefficients.

38 Prof. McFadden's model allows the estimated impact of the alleged kickbacks to vary across 12 monthly lags, but not to vary across doctors. This is curious because the damages calculation he describes depends critically upon a finding of influence at the doctor (and month) level. Nevertheless, because it is not computationally feasible to estimate a model with both lag-specific and doctor-specific impacts, I estimate an average impact across time lags, but allow for doctor-specific impacts. This is a more relevant specification given the damages methodology described by Prof. McFadden. In any case, before adding such doctor-specific impacts, I confirmed that I obtained average lagged impacts that were consistent with Prof. McFadden's original model.

doctor-specific impacts is consistent with variation associated with numerous confounding factors inappropriately omitted from Prof. McFadden's model (among other reasons).

(31) Even for purposes of testing aggregate impact, Prof. McFadden's model is unreliable because it fails to control for numerous confounding factors, which biases its estimates of the impact of the alleged kickbacks on prescribing of subject drugs. Although Prof. McFadden acknowledges that factors other than the alleged kickbacks "could contribute to differences in levels of prescription rates between doctors," his model attempts to control for such confounding factors only by including doctor-specific and time-period-specific fixed effects.[39] However, these fixed effects fail to control for any confounding factors that vary over time for a given doctor.[40] For example, the fixed effects in Prof. McFadden's model would not control for the effect on prescribing of doctor-specific promotion such as detailing, sampling, and other non-challenged events (e.g., lunch-and-learn events). Similarly, the fixed effects in Prof. McFadden's model would not control for changes in a given doctor's practice over time that could impact prescribing, such as growth in the number of patients or growth in the number of patients needing antihypertension drugs.

(32) The omission of confounding factors from Prof. McFadden's model has a dramatic impact on the results. For example, simply including variables that measure detailing, sampling, and non-challenged events, as well as doctors' prescribing of competing non-Novartis drugs, reduces the estimated incremental impact of the alleged kickbacks measured by the model by more than 50%. In other words, more than half of the incremental prescribing that Prof. McFadden's model attributes to the alleged kickbacks is actually explained by non-challenged promotion and doctors' prescribing of competing non-Novartis drugs. Moreover, when I include these additional variables, the model results for Exforge HCT, Tekturna HCT, Valturna, and Starlix no longer meet Prof. McFadden's own tests of overall statistical significance.[41] Hence, Prof. McFadden would have concluded that there was no aggregate causation for these four drugs, and he would have excluded them from his damages calculations as he does for Tekamlo and Lotrel after generic entry.

(33) Prof. McFadden's model also omits numerous other factors that are known to influence doctor prescribing, but for which data are not available. For example, third-party payors use formularies and preferred drug lists to influence doctors' prescribing. Similarly, other manufacturers' marketing should influence doctors' prescribing of Novartis's subject drugs. To demonstrate the unreliability of Prof. McFadden's model, I perform a "placebo" or "false positive" test in which I use his model to estimate the impact of the alleged kickbacks on doctors' prescribing of non-Novartis antihypertension

[39] McFadden Report, ¶¶ 37, 43.

[40] Jushan Bai, "Panel Data Models with Interactive Fixed Effects," Econometrica – Journal of Economic Society: Vol. 77, Issue 4 (July 2009), pp. 1229–79.

[41] Prof. McFadden's model is also unreliable because he fails to account for significant serial correlation in prescribing, which causes him to overstate the statistical significance of his conclusions. Indeed, when I use a standard procedure to correct his model for serial correlation, the same four drugs—Exforge HCT, Tekturna HCT, Valturna, and Starlix—fail Prof. McFadden's own tests of overall statistical significance.

drugs. If Prof. McFadden's model reliably tested for causation, I should not find that Novartis's alleged kickbacks influenced prescribing of non-Novartis antihypertension drugs. However, to the contrary, I find that Prof. McFadden's model would conclude that Novartis's alleged kickbacks caused increased prescribing of non-Novartis antihypertension drugs. This unexpected result confirms that Prof. McFadden's model does not reliably test for causation.

(34) Prof. McFadden's model is also corrupted by significant errors in the construction of his input data, as follows:

- Dr. Goldberg overstates event attendances that match his purported kickback criteria through two significant errors in his analysis of Novartis's Concerto data. First, Dr. Goldberg erroneously includes numerous events that are categorized as roundtable events in Novartis's data, but appear to have been lunch-and-learn events taking place at doctors' offices.[42] Although Dr. Goldberg excludes numerous lunch-and-learn events (which are not challenged by the government), he still includes approximately 75,000 (about 21% of the total 363,000 events) additional lunch-and-learn events in his analysis of challenged conduct.[43] Second, Dr. Goldberg erroneously double counts the cost of meals for numerous multiproduct events, which causes him to overstate the frequency of events with per-participant spending on meals that exceeds $125. When I re-calculate Prof. McFadden's damages, but exclude the additional lunch-and-learn events and correct the spending on meals at multiproduct events, damages under Prof. McFadden's methodology are reduced from $513.6 million to $445.8 million.
- Dr. Goldberg's and Prof. McFadden's analyses also include pre-2010 events for Diovan, Exforge, and Tekturna, as well as pre-2010 prescriptions and events for Diovan HCT, Exforge HCT, and Tekturna HCT, which I have been instructed is not appropriate in light of the prior settlement.[44] When I exclude pre-2010 Diovan, Exforge, and Tekturna events, damages under Prof. McFadden's methodology are reduced from $513.6 million to $228.3 million. Similarly, when I exclude pre-2010 Diovan, Exforge, Tekturna, Diovan HCT, Exforge HCT, and Tekturna HCT events and prescriptions, damages under Prof. McFadden's methodology are reduced to $119.5 million.
- Prof. McFadden inappropriately includes approximately $15.9 million in damages allegedly suffered by the government through managed Medicaid programs. Because those programs are

[42] As I explain in section IV.B, the distinction between roundtable events and lunch-and-learn events is that the former take place outside the doctor's office whereas the latter take place at the doctor's office.

[43] I identify additional lunch-and-learn events by reviewing the location of the event. Specifically, I identify roundtable events as lunch-and-learns if the event location or location type suggests the event took place in a doctor's office. For more detail, *see* Appendix F.

[44] In addition to my instruction from counsel, I note that Novartis did not generally distinguish between Diovan and Diovan HCT events, Exforge and Exforge HCT events, and Tekturna and Tekturna HCT events in the event data relied upon by Dr. Goldberg and Prof. McFadden. *See* Goldberg Report, p. 19, fn. 27. Hence, my instruction from counsel to exclude Diovan HCT, Exforge HCT, and Tekturna HCT events and prescriptions is consistent with Novartis's contemporaneous documentation.

administered by private third-party payors (similar to Medicare Part D), and because the government typically pays a capitated per-member-per-month rate, the challenged conduct likely would not have impacted the government through managed Medicaid programs.[45]

(35) Prof. McFadden's calculations do not correspond to any reliable measure of economic damages for several reasons, as follows:

- Prof. McFadden's damages calculations are based upon the total prescriptions reimbursed by the government programs for providers and time periods where he asserts they were influenced by alleged kickbacks (i.e., 8.5 million prescriptions), not the incremental prescriptions purportedly resulting from the challenged conduct (i.e., 381,000 prescriptions). Economic damages should be based upon incremental expenditures the government incurred allegedly due to the challenged conduct, not the total expenditures (which includes expenditures that the government would have incurred even in the absence of the challenged conduct).
- Prof. McFadden fails to account for substantial Medicaid and TRICARE rebates received by the government for subject drug utilization.[46] Even if the government were entitled to recover reimbursements made by government programs, damages should be based upon net government expenditures, not gross expenditures.
- Prof. McFadden's damages fail to account for costs that the government would have incurred but-for the challenged conduct. Specifically, Prof. McFadden's damages inappropriately include dispensing fees, which would have been paid by government programs regardless of which antihypertension (or antidiabetic) drug was dispensed. Similarly, Prof. McFadden fails to account for the costs of other drugs that would have been prescribed but-for the challenged conduct.

(36) While I am not able to correct all of the flaws in Prof. McFadden's model, the correction of those that I can address reduces his damages substantially. Specifically, as shown in Figure 2, correcting Prof. McFadden's model to account for some confounding factors and test for doctor-specific influence, reduces his damages to $229.5 million. Correcting for the errors in Prof. McFadden's input data further reduces his damages to $41.7 million. Finally, calculating economic damages further reduces his damages to $33.7 million.[47] For each of these scenarios, calculating damages based upon incremental claims, as is appropriate from the standpoint of economics, reduces Prof. McFadden's damages by at least 95%. After correcting these errors in Prof. McFadden's model, data inputs, and

[45] Unlike Medicare Part D, Prof. McFadden has not provided any analysis of government impact under managed Medicaid. Hence, there is no evidence that the government suffered any impact under managed Medicaid programs.

[46] Rebates for Medicare Part D drug utilization are implicitly included in Prof. McFadden's government impact calculations.

[47] It is inappropriate to adjust for both rebates and drugs that would have been prescribed but-for the alleged conduct. Here I adjust Prof. McFadden's damages by accounting for rebates and dispensing fees and excluding managed Medicaid claims.

damages calculations, I conclude that the economic impact of the alleged conduct is no more than $50 thousand.[48]

Figure 2: Prof. McFadden's damages (in millions) after corrections to his analyses

Scenario	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Correcting for errors in input data[49]	$100.1	$2.4	$41.7	$0.1
Correcting for errors in input data and calculating economic damages[50]	$81.2	$1.9	$33.7	<$0.1

Source: Concerto event data; Government claims data; IMS Health; McFadden Report; McFadden supplemental materials; Novartis details data; Novartis samples data.

(37) The remainder of this report proceeds as follows:

- In section IV, I provide relevant background information concerning the subject drugs, pharmaceutical promotion, and government health insurance programs;
- In section V, I discuss the economics of pharmaceutical promotion and explain my opinion that Novartis's challenged conduct is consistent with repeated promotion;
- In section VI, I explain why Prof. McFadden's model does not test for influence at the doctor level;
- In section VII, I explain why Prof. McFadden's model is unreliable even to test for aggregate influence;
- In section VIII, I explain how Prof. McFadden's regression model is corrupted by numerous errors in data inputs prepared by Dr. Goldberg; and
- In section IX, I explain why Prof. McFadden's calculations do not correspond to any reliable measure of economic damages.

[48] For the purpose of this Report, I assume that the government is relying on Prof. McFadden's supplemental materials. In Appendix E I provide a version of Figure 2 that corrects Prof. McFadden's original damages calculations.

[49] This consists of removing the additional lunch-and-learn events Dr. Goldberg fails to exclude, correcting Dr. Goldberg's double counting of meal spend at some multiproduct events, removing events for Diovan, Exforge, and Tekturna [hereinafter DET] events prior to 2010, and removing events and claims for DET HCT events prior to 2010.

[50] In addition to the corrections to the input data, this consists of deducting rebates, deducting dispensing fees, and excluding managed Medicaid claims.

IV. Factual background

(38) In this section, I set forth factual background information relevant to my analysis of the government's allegations. Specifically, I discuss:

- Background information about the subject drugs and my understanding of the medical conditions for which the subject drugs are indicated;
- Pharmaceutical promotion; and
- Relevant government health insurance programs.

IV.A. Subject drugs

(39) The government's allegations concern ten brand-name self-administered prescription drugs marketed by Novartis. Nine of those drugs are indicated for treatment of hypertension and the tenth is indicated for treatment of type 2 diabetes. Figure 3 below summarizes selected information about each of the ten subject drugs. As shown in Figure 3, seven of the ten subject drugs were the first drugs launched within their respective treatment classes. For example, Lotrel was the first combination of an angiotensin converting enzyme (ACE) and calcium channel blocker (CCB) and Tekturna was the first Renin Inhibitor (RI). Also, as Prof. McFadden has noted, only two subject drugs—Lotrel and Starlix—faced entry of a generic equivalent prior to 2011.[51] An additional four of the subject drugs faced generic entry from 2012 to 2014. The remaining four subject drugs have yet to face generic entry. Finally, Figure 3 shows total payments by the relevant government programs over the period 2004–2015, excluding payments for products and years released under the prior settlement (as interpreted by the government).

[51] McFadden Report, ¶ 19 and Table 1.

Figure 3: Subject drugs

Indication	Drug	Drug class	FDA approval	First drug in class?	FDA generic approval	Government reimbursements (in millions)
Hypertension	Lotrel	ACE + CCB	Mar 1995	Yes	May 2007	$1,500.8
	Diovan	ARB	Dec 1996	No	June 2014	$5,259.6
	Diovan HCT	ARB + HCT	Mar 1998	No	Sept 2012	$4,052.8
	Tekturna	RI	Mar 2007	Yes	N/A	$346.0
	Tekturna HCT	RI + HCT	Jan 2008	Yes	N/A	$84.0
	Exforge	CCB + ARB	June 2007	Yes	Mar 2013	$719.9
	Exforge HCT	CCB + ARB + HCT	Apr 2009	Yes	Sept 2012	$190.3
	Valturna	RI + ARB	Sept 2009	Yes	N/A	$36.8
	Tekamlo	RI + CCB	Aug 2010	Yes	N/A	$5.3
Diabetes	Starlix	Meglitinide	Dec 2000	No	Sept 2009	$304.1

Source: Food and Drug Administration. "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations." Accessed between March 2016 and August 2017, https://www.accessdata.fda.gov/scripts/cder/ob/; Government claims data.

Note: Government reimbursements for Diovan, Exforge, and Tekturna are limited to 2010–2015.

(40) In the remainder of this section, I discuss my understanding of the treatment of hypertension and type 2 diabetes and provide background information on each of the subject drugs.

IV.A.1. Hypertension medications

(41) About one third of Americans, and 65% over the age of 60, have hypertension.[52] Over one-half of the adult hypertensive population has publicly financed insurance: approximately 42% are covered by Medicare and approximately 12% are covered by Medicaid.[53] Among people age 65 and older with hypertension, almost all are covered by public healthcare programs.[54] Hypertensive patients are often seen by primary care providers, general practitioners, or cardiologists.[55]

(42) The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC) periodically releases recommendations regarding the diagnosis and treatment of hypertension. The 2004 JNC 7 report provides an algorithm for diagnosis and treatment of hypertension. The first line recommended treatment is adopting a more active lifestyle. If physical activity alone does not lower the patient's blood pressure to the target range, providers are

[52] National Heart, Lung, and Blood Institute, "High Blood Pressure," accessed Feb. 25, 2016, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0062996/#nhlbisec-treatment.

See also National Heart, Lung, and Blood Institute, "Risk Factors for High Blood Pressure," accessed Feb. 25, 2016, http://www.nhlbi.nih.gov/health/health-topics/topics/hbp/atrisk.

[53] National Academy on an Aging Society, "Hypertension," accessed Apr. 4, 2016, http://www.civicengagement.org/agingsociety/pdf/hypertension.pdf.

[54] National Academy on an Aging Society, "Hypertension," accessed Apr. 4, 2016, http://www.civicengagement.org/agingsociety/pdf/hypertension.pdf.

[55] WebMD, "High Blood Pressure - When to Call a Doctor," accessed December 11, 2017, https://www.webmd.com/hypertension-high-blood-pressure/tc/high-blood-pressure-hypertension-when-to-call-a-doctor

recommended to prescribe antihypertension drugs. The initial choice of drug prescribed may vary based upon the patient's (1) levels of hypertension and (2) pre-existing medical conditions such as diabetes and certain metabolic syndromes.[56]

(43) There are several different classes of antihypertension drugs, including:

- Diuretics;
- Beta blockers;
- Angiotensin-converting-enzyme (ACE) inhibitors;
- Angiotensin II receptor blockers (ARBs);
- Calcium channel blockers (CCBs);
- Alpha blockers;
- Alpha-beta blockers;
- Nervous system inhibitors;
- Vasodilators; and
- Renin inhibitors (RIs).[57]

(44) I understand that drugs in all of these classes work to lower a patient's blood pressure, but do so via different mechanisms of action. In the event that monotherapy drug treatment proves ineffective, doctors can prescribe a combination of two or more antihypertension drugs from different classes.[58] Combination therapy can include administering the relevant components individually or through a fixed-dose, single-pill combination product that incorporates some or all of the desired components.

(45) In the following paragraph, I provide background information concerning each of the nine subject antihypertension drugs.

- Lotrel: In March 1995, the FDA approved the first ACE-CCB combination product, Lotrel, which combines amlodipine besylate (an ACE) and benazepril hydrochloride (a CCB).[59] In May 2007,

[56] Department of Health & Human Services National Institute of Health, "The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure," p. 12, *available at* https://www.nhlbi.nih.gov/files/docs/guidelines/jnc7full.pdf.

[57] National Heart, Lung, and Blood Institute, "High Blood Pressure," accessed Feb. 25, 2016, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0062996/#nhlbisec-treatment.

[58] National Academy on an Aging Society, "Hypertension," accessed Apr. 4, 2016, http://www.civicengagement.org/agingsociety/pdf/hypertension.pdf.

[59] U.S. Food and Drug Administration, "Lotrel," *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020364s061lbl.pdf. U.S. Food and Drug Administration, Lotrel background, *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process

the FDA approved a generic version of Lotrel.[60] Prior to generic entry, Lotrel achieved approximately 4.0% share of antihypertension prescriptions.[61]

- Diovan: In December 1996, the FDA approved Diovan, an ARB containing the active ingredient valsartan.[62] In June 2014, the FDA approved a generic version of Diovan.[63] During the period at issue (2002–2011) Diovan achieved approximately 4.0% share of antihypertension prescriptions.
  - Diovan HCT: In March 1998, the FDA approved Diovan HCT, a combination ARB plus diuretic containing valsartan and hydrochlorothiazide.[64] In September 2012, the FDA approved a generic version of Diovan HCT.[65] During the period from its launch through the end of the period at issue, Diovan HCT achieved approximately 3.3% share of antihypertension prescriptions.
- Tekturna: In March 2007, the FDA approved the first RI, Tekturna, with an active ingredient aliskiren hemifumarate.[66] There is currently no approved generic version of Tekturna.[67] During the period from its launch through the end of the period at issue, Tekturna achieved approximately 0.3% share of antihypertension prescriptions.
  - Tekturna HCT: In January 2008, the FDA approved Tekturna HCT, a combination RI plus diuretic containing aliskiren hemifumarate and hydrochlorothiazide.[68] There is currently no approved generic version of Tekturna HCT.[69] During the period from its launch through the end of the period at issue, Tekturna HCT achieved approximately 0.1% share of antihypertension prescriptions.

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60 Law360, "Court Lifts Order Barring Teva's Generic Lotrel," accessed December 11, 2017, https://www.law360.com/articles/25160/court-lifts-order-barring-teva-s-generic-lotrel

61 Lotrel's share reduces to 2.2% when considering the entire period at issue. The shares presented here are conservative in that they do not include all antihypertension drug classes. The IMS Health data produced in this matter appear to be limited to classes containing a subject drug or molecule in a subject combination drug. For example, the IMS Health data lack any prescribing information for beta blockers.

62 U.S. Food and Drug Administration, "Diovan," *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021283s033lbl.pdf

63 Diovan's patent expired in 2012, but Ranbaxy failed to get approval for a generic until 2014 due to quality control issues. International Business Times, "Ranbaxy Gets FDA Approval for Novartis's Diovan Generic." accessed Feb. 22, 2016, http://www.ibtimes.com/ranbaxy-gets-fda-approval-novartiss-diovan-generic-1613486.

64 U.S. Food and Drug Administration, "Diovan HCT," *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020818s049lbl.pdf

65 Forbes, "Another One Bites the Dust: Diovan Patent Expires But Generic Valsartan Is MIA," accessed Sep. 13, 2016, https://www.forbes.com/sites/larryhusten/2012/09/25/another-one-bites-the-dust-diovan-patent-expires-but-generic-valsartan-is-mia/#439d5e152833.

66 U.S. Food and Drug Administration, "Tekturna," *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021985s012lbl.pdf

67 eMedTV, "Generic Tekturna," accessed Sept. 27, 2017, http://blood-pressure.emedtv.com/tekturna/generic-tekturna.html.

68 U.S. Food and Drug Administration, "Tekturna HCT," *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022107s023lbl.pdf

69 eMedTV, "Generic Tekturna HCT," accessed Nov. 9, 2017, http://hypertension.emedtv.com/tekturna-hct/generic-tekturna-hct.html

- Exforge: In June 2007, the FDA approved the first CCB-ARB combination product, Exforge, which combines amlodipine besylate (a CCB) and valsartan (an ARB).[70] In March 2013, the FDA approved a generic version of Exforge.[71] During the period from its launch through the end of the period at issue, Exforge achieved approximately 0.5% share of antihypertension prescriptions.
  - Exforge HCT: In April 2009, the FDA approved the first CCB-ARB plus diuretic product, Exforge HCT, which combines amlodipine besylate, valsartan, and hydrochlorothiazide.[72] In September 2012, the FDA approved a generic version of Exforge HCT.[73] During the period from its launch through the end of the period at issue, Exforge HCT achieved approximately 0.1% share antihypertension prescriptions.
- Valturna: In September 2009, the FDA approved the first RI-ARB combination product, Valturna, which contains aliskiren hemifumarate (an RI) and valsartan (an ARB).[74] There is currently no approved generic version of Valturna.[75] During the period from its launch through the end of the period at issue, Valturna achieved 0.1% share of antihypertension prescriptions.
- Tekamlo: In August 2010, the FDA approved the first RI-CCB combination product, Tekamlo, which contains aliskiren hemifumarate (an RI) and amlodipine besylate (a CCB).[76] There is currently no approved generic version of Tekamlo.[77] During the period from its launch through the end of the period at issue, Tekamlo achieved approximately 0.0% share of antihypertension prescriptions.

IV.A.2. Type 2 diabetes medications

(46) In 2012, approximately 30 million Americans, almost 10% of the U.S. population, had diabetes.[78] Type 2 diabetes accounts for approximately 90% of the diabetic population, with type 1 (or juvenile)

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[70] U.S. Food and Drug Administration, "Exforge," *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021990s016lbl.pdf

[71] Department of Health & Human Services, Letter to J. Picurro regarding ANDA 090011, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/090011Orig1s000ltr.pdf.

[72] U.S. Food and Drug Administration, "Exforge HCT," *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022314s011lbl.pdf

[73] Department of Health & Human Services, Letter to J. Derstine regarding ANDA 200435 (Sept. 25, 2012), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/200435Orig1s000ltr.pdf.

[74] ADVFN, "PRESS RELEASE: Novartis Receives FDA Approval For Valturna, A Single-Pill Combination Of Valsartan And Aliskiren, To Treat High," accessed Sept. 27, 2017, http://www.advfn.com/commodities/CommoditiesNews.asp?article=39519925&headline=press-release-novartis-receives-fda-approval-for-valturna.

[75] eMedTV, "Generic Valturna," accessed Sept. 27, 2017, http://blood-pressure.emedtv.com/valturna/generic-valturna.html.

[76] U.S. Food and Drug Administration, "Tekamlo," *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022545s012lbl.pdf

[77] eMedTV, "Generic Tekamlo," accessed Sept. 27, 2017, http://blood-pressure.emedtv.com/tekamlo/generic-tekamlo.html.

[78] American Diabetes Association, "Statistics About Diabetes," accessed Feb. 24, 2016, http://www.diabetes.org/diabetes-

diabetes accounting for the remaining 10%.[79] Nearly 12 million Americans (approximately 26%) aged 65 and older are estimated to have diagnosed or undiagnosed type 2 diabetes.[80] About 40% of the diabetic population is older than age 65.[81]

(47) Depending upon the severity, type 2 diabetes may be symptomatic or asymptomatic.[82] Consequently, testing to detect type 2 diabetes is recommended for adults of any age who are overweight or obese and who have one or more additional risk factors.[83] Patients with type 2 diabetes are often seen by primary care providers, family practice doctors, internists, or endocrinologists.[84]

(48) According to medical treatment guidelines, the first-line drug treatment for type 2 diabetes is metformin, an active pharmaceutical ingredient first approved by the FDA is 1995.[85] However, if metformin alone does not achieve the target blood sugar levels, then additional drug treatments using different molecules with different mechanisms of action are recommended.[86] These additional molecules include:

- Sulfonylureas, such as glyburide (DiaBeta and Glynase), glipizide (Glucontrol), and glimepiride (Amaryl);
- Meglitinides, such as repaglinide (Prandin) and nateglinide (Starlix);
- Thiazolidinediones, such as rosiglitazone (Avandia) and pioglitazone (Actos);
- DPP-4 inhibitors, such as sitagliptin (Januvia), saxagliptin (Onglyza) and linagliptin (Tradjenta); and
- SGLT2 inhibitors such as canagliflozin (Invokana) and dapagliflozin (Farxiga).[87]

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basics/statistics.

79 National Center for Biotechnology Information, U.S. National Library of Medicine, "Type 2 Diabetes," accessed Feb. 24, 2016, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0024703.

80 American Diabetes Association, "Statistics About Diabetes," accessed Feb. 24, 2016, http://www.diabetes.org/diabetes-basics/statistics.

81 Kaiser Family Foundation, "Total Number of Adults with Diagnosed Diabetes by Age Group," accessed Apr. 25, 2016, http://kff.org/other/state-indicator/adults-with-diabetes-by-age.

82 American Diabetes Association, "Diagnosing Diabetes and Learning About Prediabetes," accessed Feb. 23, 2016, http://www.diabetes.org/diabetes-basics/diagnosis.

83 American Diabetes Association, "Diabetes Care: Classification and Diagnosis of Diabetes," accessed Feb. 24, 2016, http://care.diabetesjournals.org/content/38/Supplement_1/S8.full.

84 American Diabetes Association, "Your Health Care Team," accessed Feb. 23, 2016, http://www.diabetes.org/living-with-diabetes/treatment-and-care/whos-on-your-health-care-team/your-health-care-team.html.

85 University of Michigan Health System, "Management of Type 2 Diabetes Mellitus" (May 2014), *available at* http://www.med.umich.edu/1info/FHP/practiceguides/diabetes/dm.pdf; *see also* DiaTribe, "JAMA Study Shows That Metformin is Safest First-Line Therapy for Type 2 Diabetes" (Nov. 24 2014), accessed Apr. 5, 2016, http://diatribe.org/issues/73/new-now-next/jama-metformin.

86 University of Michigan Health System, "Management of Type 2 Diabetes Mellitus" (May 2014), *available at* http://www.med.umich.edu/1info/FHP/practiceguides/diabetes/dm.pdf.

87 University of Michigan Health System, "Management of Type 2 Diabetes Mellitus" (May 2014), *available at*

(49) Over time, manufacturers have developed products that combine metformin with one or more of these additional molecules. Examples of such combination products include: Metaglip (metformin and glipizide), Glucovance (metformin and glyburide), Actoplus Met (metformin and pioglitazone), Prandimet (metformin and repaglinide), Avandamet (metformin and rosiglitazone), Invokamet XR (metformin and canagliflozin), Janumet (metformin and sitagliptin), Jentadueto XR (metformin and linagliptin), Kombiglyze XR (metformin and saxagloptin), and Xigduo XR (metformin, dapagliflozn, and propanediol).

(50) In December 2000, the FDA approved Starlix "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."[88] The active ingredient in Starlix is nateglinide, which is in a class of meglitinides that stimulate beta cells in the pancreas to release insulin.[89] In September 2009, the FDA approved a generic version of Starlix.[90] During the period from 2002 through generic entry, Starlix achieved a 1.2% share of antidiabetic prescriptions.

IV.B. Pharmaceutical promotion

(51) Promotion of brand-name pharmaceuticals takes a variety of forms. Some pharmaceutical promotion, including television and certain print media advertising, is targeted directly to patients. This type of pharmaceutical promotion is referred to as direct-to-consumer (DTC) marketing. Pharmaceutical manufacturers spent an estimated $4.2 billion on DTC marketing in 2005.[91]

(52) However, most pharmaceutical promotion is targeted to doctors and other healthcare professionals who prescribe drugs. Indeed, one of the most common forms of pharmaceutical promotion is detailing, in which sales associates visit healthcare professionals to engage in an oftentimes brief discussion of approved marketing messages for one or more brand-name drugs. Pharmaceutical manufacturers spent approximately $6.8 billion on detailing in 2005.[92] In addition, depending upon the class of drug being promoted, sales associates frequently provide free samples for healthcare professionals to give to patients starting new drug therapies. This practice is referred to as sampling.

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http://www.med.umich.edu/1info/FHP/practiceguides/diabetes/dm.pdf.

88 Novartis, "Starlix (nateglinide) Tablets," *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021204s014lbl.pdf.

89 American Diabetes Association, "What Are My Options?" accessed Feb. 23, 2016, http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/oral-medications/what-are-my-options.html

90 Par Pharmaceuticals, Dr. Reddy's Laboratories, and Teva Pharmaceuticals all gained approval for generic Starlix on September 9, 2009; *see, e.g.*, Department of Health & Human Services, Letter to K. Sekar regarding ANDA 77-461 (Sept. 9, 2009), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/077461s000ltr.pdf.

Reuters, "UPDATE 1-Dr. Reddy's Launches Generic Starlix, Shares Rise" (Sept. 14, 2009), *available at* http://www.reuters.com/article/drreddys-generic-idUSBOM45855920090914.

91 Julie M. Donohue, et al. "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," New England Journal of Medicine, Table 1, accessed Sept. 27, 2017, http://www.nejm.org/doi/full/10.1056/NEJMsa070502#t=articleMethods.

92 Julie M. Donohue, et al. "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," New England Journal of Medicine, Table 1,accessed Sept. 27, 2017, http://www.nejm.org/doi/full/10.1056/NEJMsa070502#t=articleMethods.

Pharmaceutical manufacturers also promote brand-name drugs through advertisements in medical and professional journals. Pharmaceutical manufacturers spent approximately $430 million on journal advertisements in 2005.[93]

(53) In addition to detailing and sampling, pharmaceutical manufacturers hold a variety of meetings and events to educate healthcare professionals and promote their brand-name drugs. These meetings and events take a variety of forms as I explain below. In total, pharmaceutical manufacturers spent approximately $2.7 billion on meetings and events in 2005.[94]

(54) For a lunch-and-learn program, a sales associate typically would provide a modest meal in a healthcare provider's office in order to facilitate a longer discussion of approved marketing materials. Lunch-and-learn programs are led by the sales associate and have one or more attendees who are not compensated for their time. The government does not challenge Novartis's lunch-and-programs. However, as I discuss in section VIII.A, Dr. Goldberg inappropriately includes numerous lunch-and-learn events that were incorrectly categorized as roundtable events in Novartis's data.

(55) I understand that Novartis's roundtable events take place outside the healthcare provider's office. The discussion may be facilitated by a healthcare professional on behalf of the manufacturer, or more commonly by a sales associate. Roundtable events may include a meal and have one or more attendees. However, none of the attendees, including any healthcare provider who helps facilitate the discussion, is compensated for their time. Effective January 2009, the Pharmaceutical Research Manufacturers of America (PhRMA) published an updated Code on Interactions with Healthcare Professionals.[95] PhRMA's 2009 Code states that "meals offered in connection with informational presentations made by field sales representatives or their immediate managers should be limited to in-office or in-hospital settings."[96] Consistent with PhRMA's 2009 code, I understand that Novartis ended roundtable events.[97]

(56) For a speaker program, a doctor who has been trained by the pharmaceutical manufacturer presents approved materials about one or more drugs and facilitates discussion among a group of healthcare professionals. Speaker programs are held in conjunction with a meal, typically dinner. Although the

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[93] Julie M. Donohue, et al. "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," New England Journal of Medicine, Table 1, accessed Sept. 27, 2017, http://www.nejm.org/doi/full/10.1056/NEJMsa070502#t=articleMethods.

[94] Todd D. Clark, PharmaHandbook: A Guide to the International Pharmaceutical Industry, 5th Ed. (Value of Insight Consulting, 2007).

[95] PhRMA, "Code on Interactions With Health Care Professionals," (2009), p. 3, *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008-1.pdf

[96] PhRMA, "Code on Interactions With Health Care Professionals" (2009), at Section 2, *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008-1.pdf.

[97] NPCLSV_LIT000060636 at 0639. NPCLSV00015272 at 5303 ("Neither Novartis Sales Representatives nor their immediate managers may participate in meals with HCPs taking place outside of the HCP's office or hospital. This includes Roundtables (i.e., programs other than Speaker Programs held outside of the HCP's office or hospital over the course of a meal) but is also relevant for other meals."); For a complete text of the 2009 PhRMA Code rule regarding roundtables, see NPCLSV_LIT001517018 at 7023.

speaker receives fair market value compensation pursuant to their consulting retention with the manufacturer, none of the attendees are compensated for their time.

(57) Manufacturers of brand-name pharmaceuticals also promote their products by negotiating rebates with payors and pharmacy benefit managers (PBMs) for favorable placement on their formularies, including those acting on behalf of government programs (e.g., Medicare Part D). Hence, rebates lower the net cost for the payors while providing preferential status for products on the formulary. Payors providing preferred drug plans for Medicare Part D reported receiving $6.5 billion in manufacturer rebates in 2008.[98]

IV.C. Government health insurance programs

(58) The government's allegations implicate three government health insurance programs that provide reimbursements for subject drugs: Medicare, Medicaid, and TRICARE. Both Medicare and Medicaid were established by the Social Security Act of 1965 and are administered by the Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS).[99] TRICARE is a healthcare program for active duty and retired military service members and their families administered by the Department of Defense.[100] I discuss each of these government programs further in this section.

IV.C.1. Medicare

(59) Medicare is a public health insurance program funded by the federal government to provide healthcare coverage for individuals 65 years of age and older as well as for persons with certain long-term chronic healthcare needs.[101] Medicare consists of several distinct programs.[102] Medicare Part A covers healthcare provided by hospitals, skilled nursing centers, nursing care centers, hospice, and home health services.[103] Medicare Part B covers healthcare provided by doctors, outpatient clinics, laboratories, and ambulance services, as well as certain durable medical equipment (DME) and

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[98] Department of Health and Human Services Office of Inspector General, "Concerns with Rebates in the Medicare Part D Program" (Mar. 2011), *available at* https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.

[99] Centers for Medicare & Medicaid Services, "Key Milestones in Medicare and Medicaid History, Selected Years: 1965–2003," Health Care Financing Review: Vol. 27, No. 2 (Winter 2005–06), p. 1, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/05-06Winpg1.pdf.

Department of HHS, "Historical Highlights," accessed Jan. 9, 2014, http://www.hhs.gov/about/hhshist.html.

[100] TRICARE, "About Us," accessed Sept. 27, 2017, https://www.tricare.mil/About.

[101] Centers for Medicare & Medicaid Services, "What Is Medicare?," accessed Aug. 26, 2014, http://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html.

[102] Centers for Medicare & Medicaid Services, "What Is Medicare?," accessed Aug. 26, 2014, http://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html.

[103] Centers for Medicare & Medicaid Services, "What Does Medicare Part A Cover?," accessed June 16, 2015, http://www.medicare.gov/what-medicare-covers/part-a/what-part-a-covers.html.

certain prescription drugs typically administered by doctors.[104] Medicare Part C (commonly referred to as Medicare Advantage) is not a separate benefit program but rather an alternative form of Medicare coverage funded by the federal government but administered by private third-party payors.[105] Medicare Part D is also a government-funded, privately-administered program providing coverage for outpatient prescription drugs through independent prescription drug plans (PDPs) since January 2006.[106] Since the advent of Medicare Part D, prescription drug coverage has also been available as an option under Medicare Part C.[107]

(60) Because the subject drugs in this matter are self-administered drugs generally distributed through retail or mail-order pharmacies, Medicare coverage is provided under Medicare Part D (since 2006). Consequently, I focus my discussion on Medicare Part D.

(61) Under Medicare Part D, CMS provides fixed per-beneficiary payments to private health insurers that administer the prescription drug benefits and, at least within certain defined limitations that I describe below, bear the risk of the beneficiaries' actual drug utilization.[108] In other words, with the exception of certain cost sharing arrangements that I describe below, CMS pays the private insurer a fixed per-beneficiary amount based upon the expected utilization of the enrolled beneficiaries across all covered prescription drugs and the private insurer bears the risk for the beneficiaries' actual utilization.

(62) Additional payments from CMS to the private insurer administering the Part D plan may arise for three reasons. First, if the actual utilization across all members covered by a given Medicare Part D plan exceeds pre-defined "risk corridors," CMS makes additional risk-sharing payments to the private insurer to partially offset the unexpectedly high utilization. Alternatively, if the actual utilization is lower than the defined risk corridors, then CMS receives a refund from the private insurer to share the benefit of the unexpectedly low utilization. Importantly, these risk-sharing calculations are made over all covered prescription drugs. Hence, even if the utilization of one drug is higher than expected, it may be offset by the lower utilization of another drug. Consequently, because the subject drugs represent only a small fraction of the spending under Medicare Part D plans, there is no basis to

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[104] Centers for Medicare & Medicaid Services, "What Does Medicare Part B Cover?," accessed June 16, 2015, http://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html.

[105] Medicare Interactive, "What Does Medicare Cover (Parts A, B, C, and D)?," accessed June 16, 2015, http://www.medicareinteractive.org/page2.php?topic=counselor&page=script&script_id=214.

[106] Jack Hoadley and Laura Summer, "Medicare Part D in Its Ninth Year: The 2014 Marketplace and Key Trends, 2006–2014," Kaiser Family Foundation (Aug. 14, 2014), p. 1, *available at* http://kff.org/medicare/report/medicare-part-d-in-its-ninth-year-the-2014-marketplace-and-key-trends-2006-2014/.

[107] Centers for Medicare & Medicaid Services, "How to Get Drug Coverage," accessed June 16, 2015, http://www.medicare.gov/sign-up-change-plans/get-drug-coverage/get-drug-coverage.html.

[108] Medicare Payment Advisory Commission, "Part D Payment System," *available at* http://www.medpac.gov/documents/payment-basics/part-d-payment-system-14.pdf?sfvrsn=0.

assume that any risk-sharing payments made by the government were caused by utilization of subject drugs.[109]

(63) Second, CMS provides "catastrophic coverage," for Medicare Part D beneficiaries whose out-of-pocket spending on prescription drugs exceeds annual thresholds associated with the Medicare Part D "coverage gap" (also commonly referred to as the "donut hole"). That is, under Medicare Part D, private insurers provide coverage for prescription drugs, subject to applicable deductibles and copayments, up to the amount of the "initial coverage limitation."[110] However, beyond the initial coverage limitation, the beneficiary is responsible for the costs of prescription drugs until the catastrophic coverage threshold is reached.[111] Once, the catastrophic coverage threshold is reached, CMS pays 80% of the costs of covered prescription drugs and the beneficiary is responsible for the remaining 20%.[112] Hence, the government could have paid some costs for utilization of subject drugs through its Medicare Part D catastrophic coverage payments.

(64) Third, CMS provides a "low-income subsidy" that pays for a portion of a qualifying Medicare Part D beneficiary's monthly premium, deductible, copayments, and coinsurance.[113] In addition, CMS covers the out-of-pocket expenses for qualifying beneficiaries during the coverage gap between the initial coverage limitation and the catastrophic coverage threshold.[114] In other words, eligible beneficiaries do not face a coverage gap. Hence, the government could have paid some costs for utilization of subject drugs through its Medicare Part D low-income subsidy payments.

(65) Subject to certain limitations concerning drug coverage and patient cost sharing, private health insurers choose how to structure and implement the specific Medicare Part D plans that they offer and specify a monthly premium. For example, different plans choose different deductibles, copayments, formularies, and other utilization management protocols and may charge different premiums. As of

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[109] Indeed, as I explained in section II, Prof. McFadden identifies only 330,000 purportedly incremental prescriptions resulting for Novartis's challenged conduct.

[110] For example, in 2011, the initial coverage limitation was $2,840. Q1 Medicare, "2011 Medicare Part D Program Information," accessed Sept. 28, 2017, https://q1medicare.com/PartD-The-2011-Medicare-Part-D-Outlook.php.

[111] For example, in 2011, the catastrophic coverage threshold was $6,447.50. Q1 Medicare, "2011 Medicare Part D Program Information," accessed Sept. 28, 2017, https://q1medicare.com/PartD-The-2011-Medicare-Part-D- . Outlook.php. Beginning in 2011, Medicare Part D plans were required to cover an increasing portion of the costs of prescription drugs incurred during the coverage gap.

[112] Kaiser Family Foundation, "The Medicare Part D Prescription Drug Benefit," *available at* http://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit.

[113] Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Benefit Manual Chapter 13 - Premium and Cost-Sharing Subsidies for Low-Income Individuals," *available at*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/Chapter13.pdf.

[114] Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Benefit Manual Chapter 13 - Premium and Cost-Sharing Subsidies for Low-Income Individuals," *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/Chapter13.pdf.

2014, there were nearly 1,200 unique Medicare Part D plans.[115] However, there were substantially more unique plans during earlier periods.[116]

(66) During the relevant time period, Medicare Part D plans generally reimbursed providers for covered brand-name drugs based upon a specified discount from AWP. For generic drugs, Medicare Part D plans typically employ the concept of Maximum Allowable Cost (MAC) to cap reimbursements at levels below the corresponding brand-name drug reimbursement rate. Medicare Part D plans also typically pay providers a small per-prescription dispensing fee.

IV.C.2. Medicaid

(67) Medicaid is a public health insurance program jointly funded by federal and state governments to provide healthcare coverage for certain individuals and families with low incomes and limited resources.[117] Unlike Medicare, however, Medicaid is a state-administered program—albeit one subject to federal funding and oversight—in which each state sets its own policies within certain federal guidelines regarding eligibility, services, and payments to providers. As part of their healthcare coverage, state Medicaid programs may voluntarily choose to cover prescription drugs in a variety of contexts, including retail pharmacies, institutional pharmacies, and physician clinics.[118] All 50 states and the District of Columbia provide at least some prescription drug benefit to Medicaid beneficiaries.[119]

(68) Pursuant to the Omnibus Budget Reconciliation Act (OBRA) of 1990, pharmaceutical manufacturers that wish to have their drugs reimbursed by state Medicaid programs must agree to pay states, through CMS, a quarterly rebate based upon the utilization of their drugs by Medicaid beneficiaries.[120] The OBRA rebate program has different provisions for brand-name drugs and generic drugs. For brand-name drugs, during the relevant time period, the Basic Unit Rebate Amount (Basic URA) was

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[115] Jack Hoadley and Laura Summer, "Medicare Part D in Its Ninth Year: The 2014 Marketplace and Key Trends, 2006–2014," Kaiser Family Foundation (Aug. 14, 2014), p. 8, http://kff.org/medicare/report/medicare-part-d-in-its-ninth-year-the-2014-marketplace-and-key-trends-2006-2014/.

[116] Jack Hoadley and Laura Summer, "Medicare Part D in Its Ninth Year: The 2014 Marketplace and Key Trends, 2006–2014," Kaiser Family Foundation (Aug. 14, 2014), p. 8, http://kff.org/medicare/report/medicare-part-d-in-its-ninth-year-the-2014-marketplace-and-key-trends-2006-2014/.

[117] Centers for Medicare & Medicaid Services, "Medicaid," accessed Jan. 9, 2014, http://www.medicare.gov/your-medicare-costs/help-paying-costs/medicaid/medicaid.html. *See also* Congressional Budget Office, "How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry" (Jan. 1996), pp. 4–5, *available at* http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/47xx/doc4750/1996doc20.pdf.

[118] Department of Health and Human Services, Office of the Inspector General, "Medicaid's Use of Revised Average Wholesale Prices" (Sept. 2001), p. 1, https://oig.hhs.gov/oei/reports/oei-03-01-00010.pdf.

[119] Department of Health and Human Services, Office of the Inspector General, "Replacing Average Wholesale Price – Medicaid Drug Payment Policy" (July 2011), p. 2, https://oig.hhs.gov/oei/reports/oei-03-11-00060.pdf.

[120] Department of Health & Human Services, "Omnibus Budget Reconciliation Act of 1993 (OBRA '93)," *available at* https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-009.pdf.

equivalent to the larger of: (1) 15.1% of the drug's Average Manufacturer Price (AMP)[121] or (2) the difference between the AMP and the "Best Price" that the manufacturer charges for the drug.[122] In addition, manufacturers must pay an Additional Unit Rebate Amount (Additional URA) if their AMPs increase at a rate greater than inflation.[123] Hence, OBRA 1990 rebates significantly reduce the government's expenditures for prescription drugs provided to Medicaid beneficiaries. Consequently, as a matter of economics, OBRA 1990 rebates should be accounted for in any analysis of damages sustained by the government in this matter.

(69) Like Medicare Part D plans, state Medicaid programs historically reimbursed providers for covered brand-name drugs based upon a specified discount from AWP. More recently, several states have shifted Medicaid reimbursements for brand-name (and generic) drugs to markups over pharmacies' Average Acquisition Cost (AAC).[124] For generic drugs, many state Medicaid programs also employed MACs to cap reimbursements. Like Medicare Part D plans, state Medicaid programs also generally pay providers a modest per-prescription dispensing fee. The 2006 HHS OIG study found that the average Medicaid dispensing fee was $4.30.[125] A 2006 Myers & Stauffer report concluded that state Medicaid dispensing fees ranged from "under $2 to over $11."[126]

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[121] AMP is defined as follows:

> AMP means, with respect to a covered outpatient drug of a manufacturer . . . for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.

Determination of AMP, 42 C.F.R. § 447.504 (2010).

[122] Best Price is defined as follows:

> The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.

Social Security Act, § 1927 (42 U.S.C. § 1396r-8); *see also* Deficit Reduction Act of 2005, Pub. L. No. 109-171, §6003, 120 Stat. 60–61 (2006). The calculations of AMP and best price exclude government purchases. The calculation of best price also excludes purchases made by a variety of special assistance programs and "nominal" transactions that fall below 10% of AMP. *See* Statement of Kathleen King, Director of Health Care, "Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States," Government Accountability Office (June 2005), p. 6.

[123] Centers for Medicare & Medicaid Services, "Unit Rebate Amount (URA) Calculation for Single Source or Innovator Multiple Source Drugs," *available at* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/ura-for-s-or-i.pdf.

[124] Centers for Medicare & Medicaid Services, "Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State—Quarter Ending September 2017," *available at*https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxreimbursement-chart-current-qtr.pdf.

[125] Department of Health and Human Services, Office of the Inspector General, "Review of the Relationship Between Medicare Part D Payments to Local, Community Pharmacies and the Pharmacies' Drug Acquisition Costs," Jan. 3, 2008, p. 8, *available at* https://oig.hhs.gov/oas/reports/region6/60700107.pdf.

[126] Myers and Stauffer LLC, "Survey of the Average Cost of Filling a Medicaid Prescription in the State of Minnesota"

(70) While most state Medicaid agencies traditionally operated under a fee-for-service (FFS) model, enrollment in Medicaid managed care programs has been increasing in recent years, with states free to design their own managed care program.[127] Under a managed care model, state Medicaid agencies contract with managed care organizations (MCOs) to provide benefits to beneficiaries, not unlike Medicare Part D.[128] Under the various MCO models, the state will typically pay a set (or capitated) rate to the MCO per beneficiary and month. Thus, any incremental prescriptions under the MCO model are not paid for by the state, but by the MCO. Hence, the challenged conduct likely would not have impacted the government through managed Medicaid programs.[129]

IV.C.3. TRICARE

(71) TRICARE is a government-funded program that provides comprehensive healthcare coverage to over 9.4 million military personnel and their families.[130] Express Scripts manages TRICARE's pharmacy benefit program and receives a fixed fee to cover the administrative costs.[131] Express Scripts forwards all costs to the government for drugs administered to TRICARE beneficiaries.[132]

(72) Since 1993, manufacturers have been required to provide drugs at a discounted price, known as the Federal Ceiling Price (FCP), to the Department of Defense (DOD) and other government agencies.[133] The FCP equates to 76% of the annual Non-Federal Average Manufacturer Price (non-FAMP), less annual increases in the non-FAMP that exceed inflation.[134] There are two methods of providing a drug at the FCP: (1) a pharmaceutical manufacturer can provide drugs at a discounted price equal to the FCP or (2) provide a rebate equal to the amount in which the price paid exceeds the FCP.

(73) Prior to January 28, 2008, manufacturers were not required to provide drugs at the FCP to TRICARE. The National Defense Authorization Act for Fiscal Year 2008 (NDAA-08) established that the

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(Dec. 26, 2006), p. 5, *available at* http://www.dhs.state.mn.us/main/groups/business_partners/documents/pub/dhs16_137108~1.pdf.

[127] Medicaid and CHIP Payment and Access Commission, "Context and Overview of Medicaid Managed Care," *available at* https://www.macpac.gov/wp-content/uploads/2015/01/Context_and_Overview_of_Medicaid_Managed_Care.pdf

[128] Centers for Medicare & Medicaid Services, "Managed Care Overview," accessed Sept. 27, 2017, https://www.medicaid.gov/medicaid/managed-care/index.html.

[129] An exception to this would be for states where their arrangement with the MCO allows for risk sharing. To the best of my knowledge, Prof. McFadden makes no attempt to identify states for which such arrangements exist.

[130] TRICARE, "TRICARE Facts & Figures," accessed Sept. 27, 2017, https://www.tricare.mil/About/Facts.

[131] InsideGov, "HT940214D0002-0005 $5.69M Contract with Express Scripts, Inc. in Saint Louis, MO," accessed Sept. 27, 2017, http://government-contracts.insidegov.com/l/18060002/HT940214D0002-0005.

[132] Department of Defense, Express Scripts Contract, p. 67, *available at* https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjBv_rg57TWAhVLxoMKHePRBfcQFggoMAA&url=https%3A%2F%2Fhealth.mil%2FReference-Center%2FFOIA-Documents%2F2015%2F07%2F08%2FExpress-Scripts-Military-Health-System-Statement-of-Work&usg=AFQjCNG5m1M-Bk48XBw-hdmxAKCWgGcggQ.

[133] 38 U.S.C. § 8126.

[134] 38 U.S.C. § 8126.

"TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the procurement of drugs."[135] Therefore, the NDAA-08 required that manufacturers provide drugs at the FCP for drugs purchased at TRICARE network retail pharmacies. The DOD enforced the NDAA-08 by offering pharmaceutical manufacturers preferred placement on TRICARE's formulary in exchange for rebates.[136] These rebates amount to–at a minimum–the difference between the actual sales price and the FCP.[137] Manufacturers must provide the DOD with rebates within 70 days of receiving the government's quarterly submission of TRICARE utilization data.[138] Consequently, as a matter of economics, rebates paid to TRICARE should be accounted for in any analysis of damages sustained by the government in this matter.

(74) Like Medicare Part D and Medicaid, TRICARE reimbursements are broken out into ingredient cost and dispensing fee components. Ingredient costs paid by TRICARE are typically the lesser of the usual and customary cost of the provider, the maximum allowable cost, or the TRICARE pharmacy's contracted rate. TRICARE's dispensing fee is the lesser of the PBM's negotiated rate with the pharmacy or the PBM's contracted rate.[139]

[135] National Defense Authorization Act for Fiscal Year 2008, H.R. 1585, 110th Cong. § 703(f) (Dec. 2007), p. 187, *available at* https://www.gpo.gov/fdsys/pkg/CRPT-110hrpt477/pdf/CRPT-110hrpt477.pdf.

[136] Lexolgy, "TRICARE Retail Pharmacy Program Subject to Federal Ceiling Prices Under New DoD Rule," accessed Sept. 28, 2017, https://www.lexology.com/library/detail.aspx?g=453ee439-8f32-4afd-a2eb-52d63f0a4dea.

[137] Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals, Fed. Reg. Vol 75, No. 199 (Oct. 15, 2010), https://www.federalregister.gov/documents/2010/10/15/2010-25712/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-inclusion-of-tricare.

[138] Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals, Fed. Reg. Vol 75, No. 199 (Oct. 15, 2010), https://www.federalregister.gov/documents/2010/10/15/2010-25712/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-inclusion-of-tricare.

[139] TRICARE, "TRICARE Reimbursement Manual 6010.58-M, Chapter 1: Legend Drugs And Insulin" (February 1, 2008), *available at* http://manuals.tricare.osd.mil/DisplayManualPdfFile/TO08/96/ChangeOnly/tr08/c1s15.pdf.

V. The government's allegations ignore the promotional purpose of repeated attendance

(75) As I explained in section I, the primary driver of alleged damages is the government's allegation that repeated attendance at Novartis's speaker and roundtable events constitutes a kickback. According to Dr. McMahon:

> …a reasonable medical provider would obtain no educational benefit from attending three or more speaker program presentations or roundtables (or a combination thereof) with respect to the same drug within a six-month period.[140]

Similarly, according to Dr. Schneller:

> …while it is possible that attendance at a single event might yield a marginal benefit to a doctor who was interested in a refresher on this material, such physicians certainly would not derive any educational benefit from attending multiple events on the same drug.[141]

According to the government's theory, if a provider received no educational benefit, the purpose of having that provider attend the event must have been to provide a kickback.

(76) Regardless of whether any particular event lacked educational benefit for a given attendee, the government's kickback theory is based upon a false dichotomy that ignores a credible alternative purpose, at least as a matter of economics, for hosting doctors repeatedly at events: promotion.[142] Consequently, it does not follow that repeated attendance of roundtable and speaker events was necessarily a kickback to healthcare providers.

(77) Since at least the 1960s, economists have recognized that marketing serves at least two primary purposes: dissemination of information (i.e., product education) and promotion (e.g., reminders, recall, brand loyalty, etc.).[143] Importantly, marketing does not need to be strictly educational (as defined by Drs. McMahon and Schneller) in order to be effective in influencing decisions. For example, detailing, a non-challenged form of promotion that contains little formal educational content

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[140] McMahon Report, ¶ 16.

[141] Schneller Report, p. 2.

[142] Dr. Schneller appears to agree with this characterization of the events. Specifically, he states "[t]he presentations are characterized by their simplicity and repetitiveness. These features, as well as the framing of the issues, the focus on a single product, the emphasis on the benefits of a Novartis drug, the duplication of presented information, and the striking simplicity of the clinical cases presented are all characteristic of pharmaceutical promotion rather than medical education." *See* Schneller Report, p. 22. *See also* Schneller Report, pp. 24–25.

[143] Kyle Bagwell, "The Economic Analysis of Advertising," Columbia University Department of Economics Discussion Paper Series, No.: 0506-01, (Aug. 2005), pp. 3–4.

in many instances, is ubiquitous within the pharmaceutical industry and known to be highly effective in influencing prescribing.[144]

(78) Successful marketing also typically requires significant repetition, both because the uptake of messages improves with additional exposure and because the impact of messages decays in the absence of additional exposure.[145] Repetition of promotional messages is evident in Novartis's promotional data. For example, nearly 65% of healthcare professionals that attended a Lotrel event also received a Lotrel detailing visit at least every other week, on average. However, the marginal impact of marketing messages typically declines with repeated exposure, a concept referred to in the marketing literature as "wear out."[146] Indeed, when I separate the impact of attending each subsequent event in Prof. McFadden's model, the impact for the third and subsequent repeat attendances within six months (the events that allegedly constitute kickbacks) is extremely small and significantly less than the impact his model would measure for the first and second attendances. Hence, the overall pattern of diminishing marginal impacts for repeated attendance is consistent with the concept of promotional wear out.

(79) In this section, I explain the economics of pharmaceutical marketing and demonstrate that the challenged events are consistent with repeated promotion.

V.A. Economics of pharmaceutical promotion

(80) Prior to the 1960s, economists paid little attention to marketing in part because, within the standard model of perfect competition—where products are assumed to be homogenous and consumers are assumed to be perfectly informed—there is little role for advertising. However, since at least the early 1960s, economists have recognized that consumers are not perfectly informed, in part because information is costly to obtain.[147] In the presence of such search costs, economic agents rationally choose whether and to what extent to acquire information and will only acquire information when the expected benefit of doing so exceeds the expected costs.[148] Within this framework, marketing plays

[144] Sridhar Narayanan and Puneet Manchanda, "Heterogeneous Learning and the Targeting of Marketing Communication for New Products," Marketing Science: Vol. 28, No. 3 (2009), pp. 425, 432.

[145] Marc Nerlove and Kenneth Arrow, "Optimal Advertising Policy under Dynamic Conditions;" Economica, Vol. 29, No. 114 (May 1962), pp. 129–142.

[146] Margaret H. Blair, "An Empirical Investigation of Advertising Wearin and Wearout," Journal of Advertising Research, 40(6), pp. 95-100. *See also* Gerard J. Tellis, "Generalizations about Advertising Effectiveness in Markets." Journal of Advertising Research, Journal of Advertising Research, June 2009, *available at* www.journalofadvertisingresearch.com/content/49/2/240.

[147] George Stigler, "The Economics of Information," Journal of Political Economy, Vol. 21, No. 3 (June 1961) p. 213.

[148] Joseph E. Stiglitz, "The Contributions of the Economics of Information to Twentieth Century," The Quarterly Journal of Economics, Vol. 115, No. 4, (Nov. 2000), pp. 1441–1478

an important role because it reduces the costs of search. Indeed, in his seminal 1961 paper that launched the field of information economics, George Stigler characterized advertising as follows:

> [Advertising] is clearly an immensely powerful instrument for the elimination of ignorance—comparable in force to the use of the book instead of the oral discourse to communicate knowledge. A small $5 advertisement in a metropolitan newspaper reaches (in the sense of being read) perhaps 25,000 readers, or fifty readers per penny, and, even if only a tiny fraction are potential buyers (or sellers), the economy they achieve in search, as compared with uninstructed solicitation, may be overwhelming.[149]

(81) Thus, one clear role that economists recognize for marketing is to disseminate information to consumers about the characteristics and prices of products and services in the market (i.e., product education).[150] However, dissemination of information is not the only recognized role for marketing. Importantly, economists also recognize the role of marketing in altering consumers' preferences and building brand loyalty.[151] That is, economists recognize that marketing does not need to be purely educational in order influence behaviors.

(82) Economists also recognize that marketing generally has a lagged effect on behavior, such that the full impact extends beyond the contemporaneous period in which the marketing occurs.[152] However, it is generally understood that the impact of marketing decays over time. For example, in their seminal paper that launched these concepts in economics, Nerlove and Arrow describe the decay of advertising effectiveness as follows:

> Regardless of its precise effects on the demand function, advertising expenditure at any one time may be expected to lose its effectiveness in subsequent periods. An advertising campaign conducted now may bring a hundred thousand customers into the fold today, but next month or next year many of these will have drifted off. Other firms and other industries do not stand still but also commit funds to advertising; these campaigns in turn draw customers to the products or brands advertised and away from the product or brand initially considered.[153]

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[149] George Stigler, "The Economics of Information," Journal of Political Economy, Vol. 21, No. 3 (June 1961), p. 220.

[150] Kyle Bagwell, "The Economic Analysis of Advertising," Columbia University Department of Economics Discussion Paper Series, No. 0506-01, (Aug. 2005), pp. 3–4.

[151] Kyle Bagwell, "The Economic Analysis of Advertising," Columbia University Department of Economics Discussion Paper Series, No. 0506-01, (Aug. 2005), p. 3.

[152] Prof. McFadden also embraces this concept through his use of lagged measures of alleged kickbacks. *See* McFadden Report, ¶¶ 49, 56.

[153] *See* Marc Nerlove and Kenneth Arrow, "Optimal Advertising Policy under Dynamic Conditions;" Economica, Vol. 29, No. 114 (May 1962), p. 130.

(83) In economic terms, marketing is considered a "stock" that increases with additional expenditures, but depreciates over time.[154] For example, Nerlove and Arrow describe the stock of advertising as follows:

> A more promising approach, and one which has considerable intuitive appeal, is to define a stock, which we shall call *goodwill* and denote by *A(t)*, and which we suppose summarizes the effects of current and past advertising outlays on demand. The price of a unit of goodwill, we shall suppose, is $1, so that a dollar of current advertising expenditure increases goodwill by a like amount. On the other hand, a dollar spent some time ago should, according to our previous argument, contribute less. One possible way of representing this lessor contribution is to say that goodwill, like many other capital goods, depreciates.[155]

(84) Based upon the standard economic model of marketing as a stock, there is a clear role for repeated promotion to counteract the effects of depreciation over time. Hence, the government's theory ignores a credible alternate explanation that the purpose of hosting doctors repeatedly at events was to expose healthcare professionals to repeated promotional messages rather than to provide kickbacks. Consequently, it does not follow that repeated attendance at roundtable and speaker events was necessarily a kickback to healthcare providers.

(85) These concepts have been applied frequently to the study of pharmaceutical marketing. For example, Frank and Zeckhauser highlight the increased cognitive burden on prescribers, which underscores the need for an educational role of pharmaceutical marketing:

> With the advance of science and medical knowledge, selecting the appropriate treatment for a patient has become a much more difficult task for a broad variety of conditions. Thirty years ago there might have been a single class of drugs (with a single mechanism of action) with a few primary drugs for treating a common condition, such as depression. [...] The advance of science has expanded the set of potential treatments for many conditions, and has increased the cognitive burden of selecting a treatment that best matches an individual patient's situation.[156]

(86) Similarly, Leffler characterizes the educational role of pharmaceutical marketing as follows:

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[154] *See* Marc Nerlove and Kenneth Arrow, "Optimal Advertising Policy under Dynamic Conditions;" Economica, Vol. 29, No. 114 (May 1962), pp. 129–142.

[155] *See* Marc Nerlove and Kenneth Arrow, "Optimal Advertising Policy under Dynamic Conditions;" Economica, Vol. 29, No. 114 (May 1962), pp. 130–131.

[156] Richard G. Frank, Richard J. Zeckhauser, "Custom-made versus ready-to-wear treatments: Behavioral propensities in physicians' choices" Journal of Health Economics 26 (2007), pp. 1103.

> Treatment of disease via drug therapy is an ever-changing technology characterized by high costs of information as to the most efficacious product.[157]
>
> The cost to the individual physician of information on a particular drug's effects (and, of course, the potentially high value of such information) provides the economic incentive for pharmaceutical firms to inform prescribers of the advantages (demand-increasing effects) of their products.[158]
>
> Such advertising can conserve resources and increase welfare not only by saving the physician time in selecting drug therapies but also by increasing the substitution of drug therapy for other treatments…and by reducing the likelihood that an inappropriate drug is prescribed.[159]

(87) Narayanan and Manchanda find evidence of both an educational and promotional role of detailing. Specifically, they state the following conclusions:

> However, it is well documented that detailing has an effect on physicians' prescription behavior even in the case of mature products (cf. Gönül et al. 2001, Manchanda and Chintagunta 2004). It has been suggested that this effect in the case of mature products may be because of an image or prestige role of detailing, or perhaps stem from reminder effects.[160]
>
> The parameter estimates for the coefficient of the linear detailing stock…suggest that there is a positive persuasive effect of detailing. Thus, even after a physician's uncertainty about the drug is reduced, there is still a positive effect of detailing.[161]
>
> Our parameter estimates indicate that there is considerable heterogeneity across physicians in terms of learning rates. Some physicians require only a few detailing calls to substantially reduce their uncertainty about a new drug. Others require many repeated detailing calls to reduce their uncertainty to the same extent. Physicians also

[157] Keith B. Leffler, "Persuasion or Information? The Economics of Prescription Drug Advertising," Journal of Law and Economics 24, No. 1 (Apr. 1981): pp. 45–74 at 53.

[158] Keith B. Leffler, "Persuasion or Information? The Economics of Prescription Drug Advertising," Journal of Law and Economics 24, No. 1 (Apr. 1981): pp. 45–74 at 54.

[159] Keith B. Leffler, "Persuasion or Information? The Economics of Prescription Drug Advertising," Journal of Law and Economics 24, No. 1 (Apr. 1981): pp. 45–74 at 56.

[160] Sridhar Narayanan and Puneet Manchanda, "Heterogeneous Learning and the Targeting of Marketing Communication for New Products," Marketing Science: Vol. 28, No. 3 (2009), p. 429.

[161] Sridhar Narayanan and Puneet Manchanda, "Heterogeneous Learning and the Targeting of Marketing Communication for New Products," Marketing Science: Vol. 28, No. 3 (2009), p. 432.

> differ significantly in the persuasive effect of detailing, which is the only effect present once they are fully knowledgeable about the drug.[162]

(88) Leffler reaches a similar conclusion:

> The empirical results developed here indicate a dual role of pharmaceutical advertising: advertising appears to inform physicians about the existence and characteristics of new products while also producing "brand-name recall" effects that favor established products facing new competition.[163]

(89) Similarly, Ching and Ishihara conclude:

> Although both effects are statistically significant, we find that the persuasive function of detailing plays a very minor role in determining the demand at the chemical level—the informative role of detailing is mainly responsible for the diffusion patterns of chemicals. In contrast, the persuasive role of detailing plays a crucial role in determining the demand for brands that comarket the same chemical.[164]

(90) Finally, I note that much of the literature analyzing pharmaceutical marketing treats marketing expenditures as a depreciating stock.[165] As I explained above, this standard economic model provides a clear rationale for repeated promotion to counteract depreciation. Consequently, it does not follow that repeated attendance of roundtable and speaker events was necessarily a kickback to healthcare providers.

V.B. The market for antihypertension drugs is consistent with the need for repeated promotion

(91) The market for antihypertension drugs is characterized by several factors that are consistent with the need for repeated promotion. First, the antihypertension drug market is a crowded market consisting of dozens of single- and combination-molecule products covering at least six classes with distinct mechanisms of actions. Second, the antihypertension drug market is a dynamic market with changes in treatment guidelines, entry of new brand-name and generic competitors, frequent clinical trials, and

[162] Sridhar Narayanan and Puneet Manchanda, "Heterogeneous Learning and the Targeting of Marketing Communication for New Products," Marketing Science: Vol. 28, No. 3 (2009), p. 439.

[163] Keith B. Leffler, "Persuasion or Information? The Economics of Prescription Drug Advertising," Journal of Law and Economics 24, No. 1 (Apr. 1981): pp. 45–74 at 47.

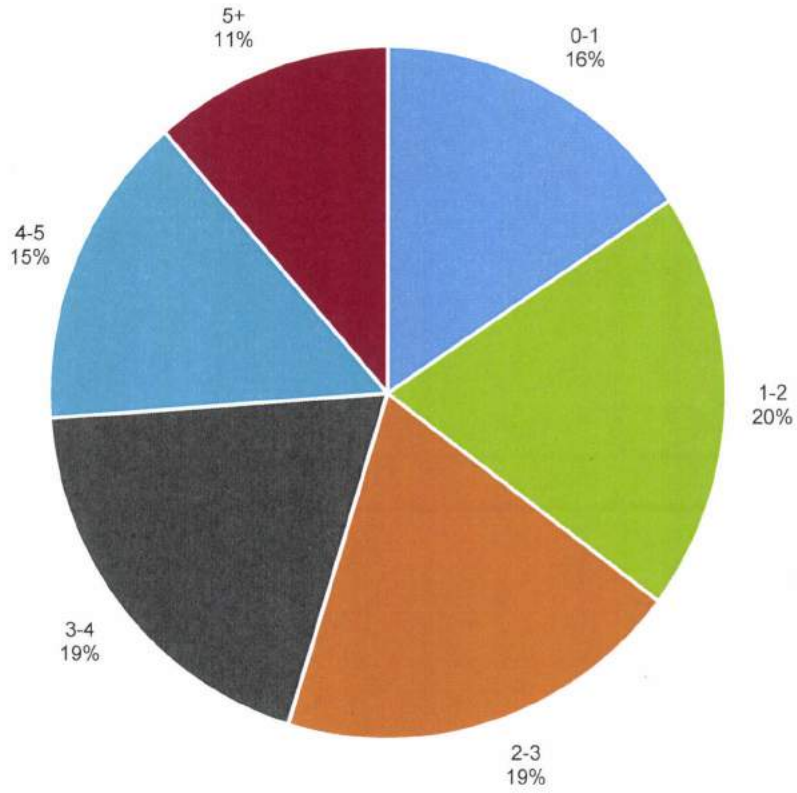
[164] Andrew T. Ching, Masakazu Ishihara, "Measuring the Informative and Persuasive Roles of Detailing on Prescribing Decisions," Management Science, Vol. 58, No. 7, (2012), pp.1374–1387.

[165] *See* Anusua Datta, and Dhaval Dave. "Effects of Physician-Directed Pharmaceutical Promotion on Prescription Behaviors: Longitudinal Evidence." Health Economics, Vol. 26, No. 4, 2016, pp. 450–468. *See also* Berndt, Ernst R, et al. "The Roles of Marketing, Product Quality, and Price Competition in the Growth and Composition of the U.S. Antiulcer Drug Industry." The Economics of New Goods, University of Chicago Press (Jan. 1996), pp. 277–328.

numerous FDA warnings and other label changes. Third, the vast majority (74%) of antihypertension prescriptions are written by general practitioners who, unlike cardiologists such as Dr. Schneller, do not generally specialize in treating hypertension or heart disease. According to NAMCS data, antihypertension drugs represent about 17% of prescriptions written by general practitioners while Novartis's subject drugs represent only about 1% of prescriptions written by general practitioners.

(92) Before discussing each of these factors in more detail, I note that the most compelling evidence of the need for repeated promotion of antihypertension drugs is the high frequency of detailing and other non-challenged marketing. Indeed, as shown in Figure 4 below, nearly 65% of healthcare professionals that attended a Lotrel event also received a Lotrel detailing visit at least every other week on average.

Figure 4: Share of providers who went to Lotrel events by average number of Lotrel details per month, 2003–2006



Source: Novartis details data.

V.B.1. The market for antihypertension drugs is crowded

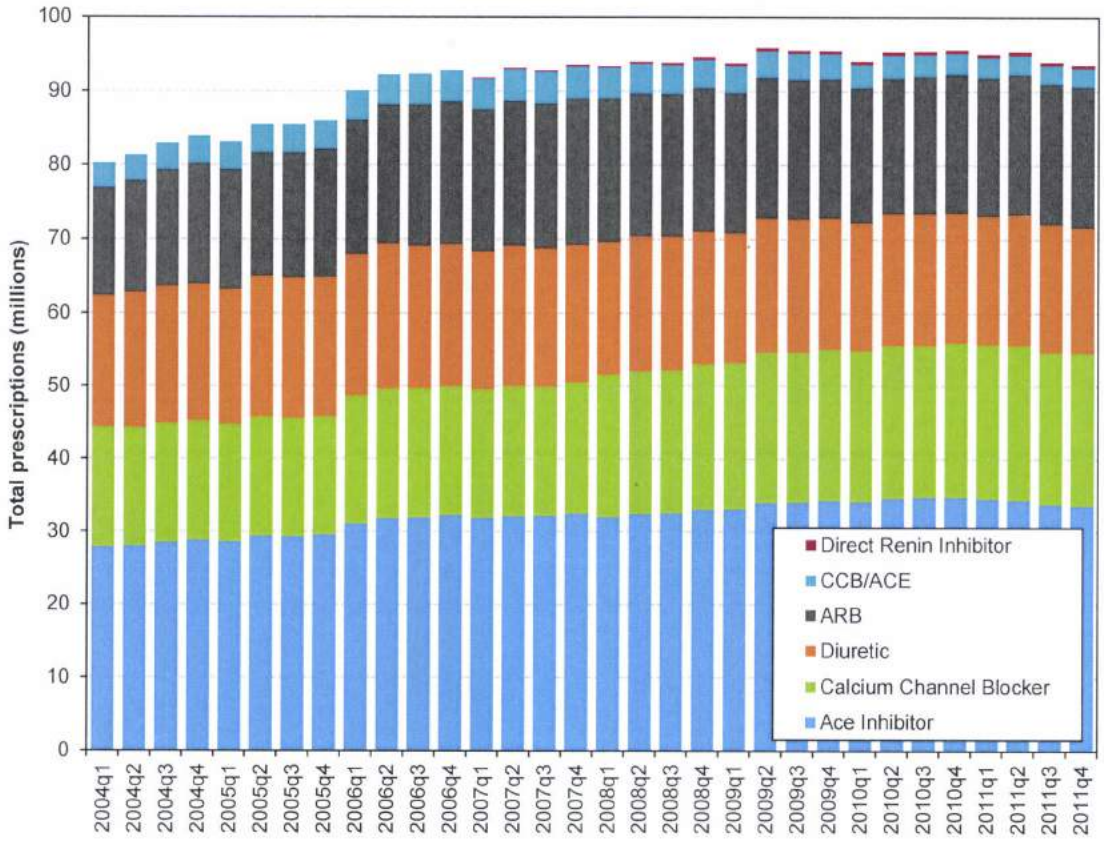
(93) The market for antihypertension drugs is crowded with dozens of single- and combination-molecule products covering at least six classes of drugs. Indeed, according to Dr. Schneller, there are twelve distinct classes of drugs used to treat hypertension, although the top five classes account for the majority of prescriptions.[166] Figure 5 below shows antihypertension prescriptions across six classes as identified by IMS Health data.[167] As shown in Figure 5, ACE inhibitors represent the most commonly prescribed antihypertension drug class followed by calcium channel blockers (CCBs) and ARBs.

[166] Schneller Report, p. 5.

[167] These figures are conservative in that they do not include all antihypertension drug classes. The IMS Health data produced in this matter appear to be limited to classes containing a subject drug or molecule in a subject combination drug. For example, the IMS Health data lack any prescribing information for beta blockers.

Direct renin inhibitors constitute the smallest (and newest) class of commonly prescribed antihypertension drugs.

Figure 5: Antihypertension prescriptions, by class



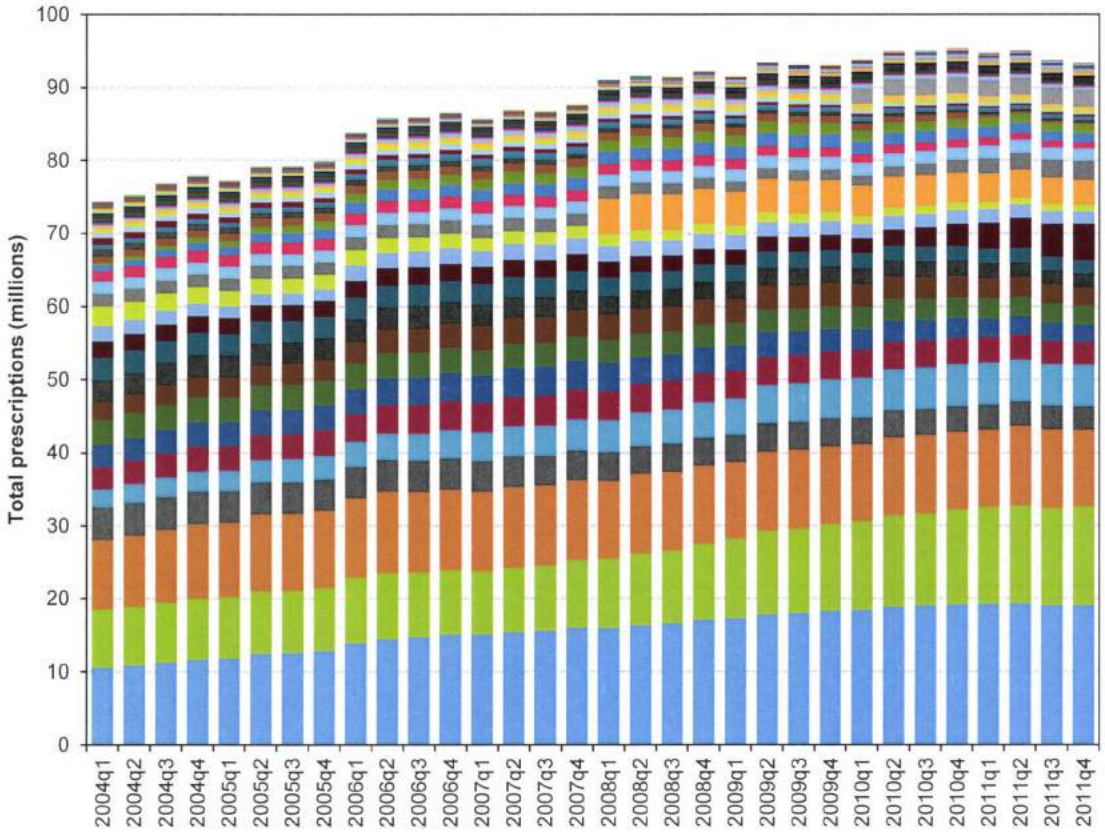
Source: IMS Health.

Note: Figure excludes 2002 and 2003 since diuretics data are unavailable prior to 2004.

(94) Figure 6 below shows antihypertension prescriptions by molecule. Notably, the IMS Health data contain a total of 63 distinct molecules with the top five molecules representing about 50% of antihypertension prescriptions. Research indicates that there are over 100 distinct antihypertension agents.[168] The most prescribed antihypertension drugs are lisinopril (a generic ACE inhibitor originally marketed by Merck and AstraZeneca under the brand-names Prinivil and Zestril), amlodipine (a generic CCB originally marketed by Pfizer under the brand name Norvasc), and hydrochlorothiazide (a generic diuretic).

[168] eMedExpert, "List of Antihypertensive Medications," accessed Nov. 3, 2017, http://www.emedexpert.com/lists/hypertension.shtml.

Figure 6: 2004-2011 Antihypertension prescriptions, by molecule[169]



Source: IMS Health.

Note: Figure excludes 2002 and 2003 since diuretics data are unavailable prior to 2004. Figure excludes products in which the molecule was indeterminate (e.g., codedesc of "AO 41210 BRANDED").

V.B.2. The market for antihypertension drugs is dynamic

(95) As shown in the figures above, the market for antihypertension drugs is far from static. Between January 2002 and December 2011, at least 34 new generic and 29 new brand-name products entered the market. Recall that, according to Nerlove and Arrow, competition is one of the primary drivers of the depreciation of marketing effectiveness and, hence, a primary motivation for repeated promotion.[170] Similarly, marketing literature discusses a competitive concept called "share of voice"

[169] Excludes prescriptions when the molecule indeterminable (e.g., the brand is "AO CCB MONTHLY GEN").

[170] Specifically, Nerlove and Arrow state, "[r]egardless of its precise effects on the demand function, advertising expenditure at any one point may be expected to lose its effectiveness in subsequent periods…Other firms and other industries do not stand still but also commit funds to advertising; these campaigns in turn draw customers away from the product or brand initially considered." *See* Marc Nerlove and Kenneth Arrow, "Optimal Advertising Policy under Dynamic Conditions;" Economica, Vol. 29, No. 114 (May 1962), pp. 129–142.

(SOV), which corresponds to the percentage of marketing activities associated with each brand in a market.[171] For example:

> [B]rands that increase their share of voice with powerful advertising stand a better chance of increasing their market share.[172]
>
> In highly competitive markets, more must be invested in advertising to increase or at least maintain market position.[173]
>
> If large-market-share brand leaders reduce their SOVs, they are vulnerable to losing market share to active competitors. On the other hand, if market followers increase their ad spending, the leading brands often follow suit to offset the competitive challenge.[174]

(96) It is my understanding that Novartis's other expert witnesses will opine that the antihypertension drug market is also characterized by evolving standards of treatment. JNC released revised treatment guidelines in 1997, 2003, and 2014. Other organizations, such as the European Society of Cardiology, the International Society on Hypertension in Blacks, and the American College of Cardiology, also released treatment guidelines during the relevant period.[175] Moreover, the treatment of hypertension continues to evolve. Indeed, the American College of Cardiologists released new hypertension treatment guidelines in November 2017 that included significant changes to the level of blood pressure that supports a diagnosis of hypertension.[176]

(97) The antihypertension drug market is also characterized by voluminous ongoing research. As an example on ongoing research, Figure 7 shows that at least 50 studies related to hypertension and one of Lotrel's active ingredients were published each year between 2002 and 2011.

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171 Business Dictionary, "Share of Voice," accessed Nov. 8, 2017, http://www.businessdictionary.com/definition/share-of-voice.html

172 Michael Solomon, Launch! Advertising and Promotion in Real Time (Boston: Flat World Knowledge, Inc., 2010), 143.

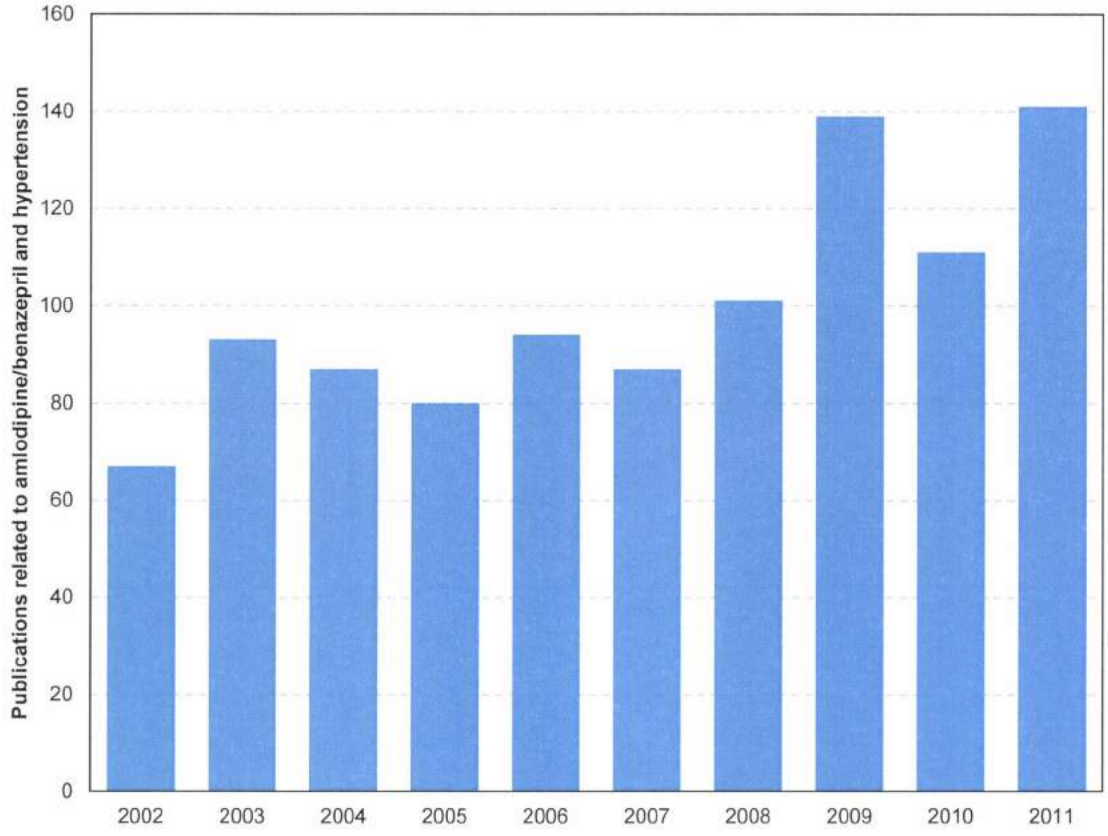
173 William Chitty, Nigel Barker, William Valos, and Terrence A Shimp, Integrated Marketing Communications (Boston: Cengage Learning, 2011), 122.

174 William Chitty, Nigel Barker, William Valos, and Terrence A Shimp, Integrated Marketing Communications (Boston: Cengage Learning, 2011), 122.

175 International Society on Hypertension in Blacks, "Management of High Blood Pressure in African Americans," *available at* http://hyper.ahajournals.org/content/56/5/780.full.pdf?download=true. *See also* European Society of Cardiology, "2007 Guidelines for the management of arterial hypertension: The Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC)," *available at* https://goo.gl/d5TjSc.

176 "American Heart Association, "2017 Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults," *available at* https://healthmetrics.heart.org/wp-content/uploads/2017/11/Detailed-Summary.pdf

Figure 7: Studies published each year related to Lotrel's active ingredients



Source: PubMed, https://www.ncbi.nlm.nih.gov/pubmed/advanced.

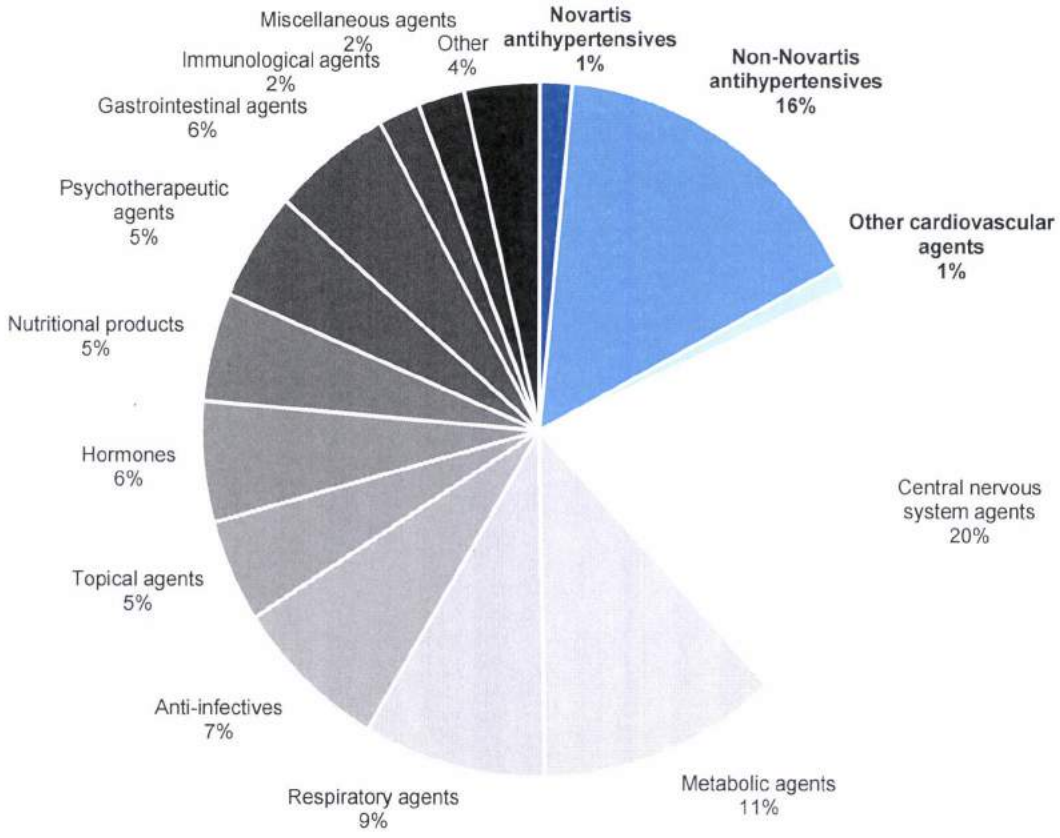
Note: Number of publications were determined using PubMed's publication search results. Publications that contained both "amlodipine" and "hypertension" or both "benazepril" and "hypertension" in the title or abstract were included for the summary above.

V.B.3. Most antihypertension prescriptions are written by general practitioners who do not specialize in treatment of hypertension

(98) Based on my analysis of IMS data, approximately 74% of all antihypertension prescriptions between 2002 and 2011 were written by primary care physicians. The significance of this observation is that primary care physicians treat patients with a wide variety of conditions including infections, respiratory disorders, gastrointestinal diseases, psychological and emotional disorders, pain, obesity, diabetes, high cholesterol, and many others in addition to treating hypertension. Hence, nearly three-fourths of all antihypertension prescriptions were written by health care professionals that, unlike cardiologists such as Dr. Schneller, do not specialize in the treatment of hypertension or cardiac diseases. Indeed, as shown in Figure 8 below, from 2002 to 2011, antihypertension drugs represented about 17% of prescriptions written by general practitioners. Similarly, Novartis's subject antihypertension drugs represented only about 1% of prescriptions written by general practitioners.

Hence, there is no *a priori* reason to believe that primary care physicians, representing 74% of all antihypertension prescriptions, would not receive educational benefits from repeated attendance of Novartis's challenged events.

Figure 8: 2002-2011 prescribing for primary care physicians, by treatment market



Source: National Ambulatory Medical Care Survey (NAMCS).

(99) In addition to treating patients with a wide variety of conditions, healthcare providers typically prescribe numerous different antihypertension drugs. I understand that Novartis's other expert witnesses will offer opinions concerning the factors that healthcare providers typically consider when prescribing antihypertension drugs. Further, Dr. Schneller highlights several of the reasons why, including:

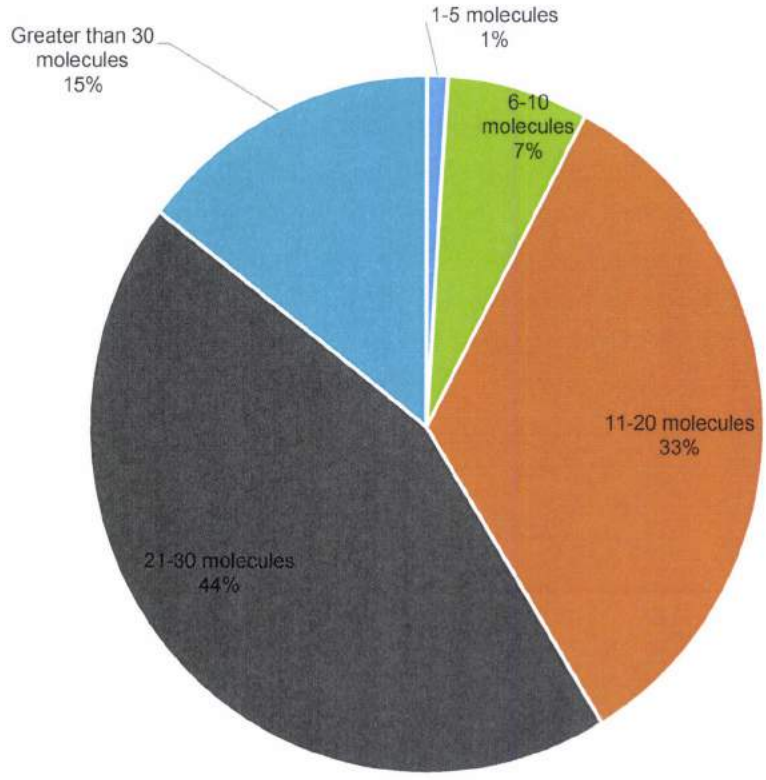
> There is wide variability among patients in response to any drug;
>
> There are few criteria that permit a patient's response to a drug to be predicted;
>
> The prescriptions of two or several drugs, each in low dose, typically produces better blood pressure control with fewer adverse effects than high doses of a single agent;

> Co-existing medical conditions, including heart failure, atrial fibrillation, cardiac conduction-system disease, diabetes, kidney disease and other ailments may influence choice of anti-hypertensive therapy; and
>
> Each class of medication may produce specific adverse effects and may require specific monitoring.[177]

(100) Regardless of the specific reasons, as shown in Figure 9 below, over 50% of providers prescribing antihypertension drugs prescribed more than 20 different molecules in 2006 and about 92% prescribed more than 10 different molecules.

[177] Schneller Report, pp. 11–12.

Figure 9: Share of doctors, by number of antihypertension drug molecules prescribed in 2006



Source: IMS Health.

Note: Limited to providers who had at least 10 antihypertension prescriptions per month, on average. These providers represent 32% of providers who prescribed antihypertension drugs in 2006, but account for 97% of antihypertension prescriptions.

V.C. Prof. McFadden's model is consistent with a promotional purpose for repeated attendance of events

(101) Prof. McFadden's model does not prove that doctors' prescribing of Novartis's subject drugs was influenced by alleged kickbacks. Even taking Prof. McFadden's results at face value, his model cannot distinguish whether the influence he purports to measure was caused by alleged kickbacks or alternatively by promotion (or education). Indeed, when I separate the impact of attending each subsequent event in Prof. McFadden's model, the impact for the third and subsequent repeat attendances within six months (the events that allegedly constitute kickbacks) is extremely small and significantly less than the impact his model would measure for the first and second attendances. This overall pattern of diminishing (but non-zero) marginal impacts for repeated attendance is consistent

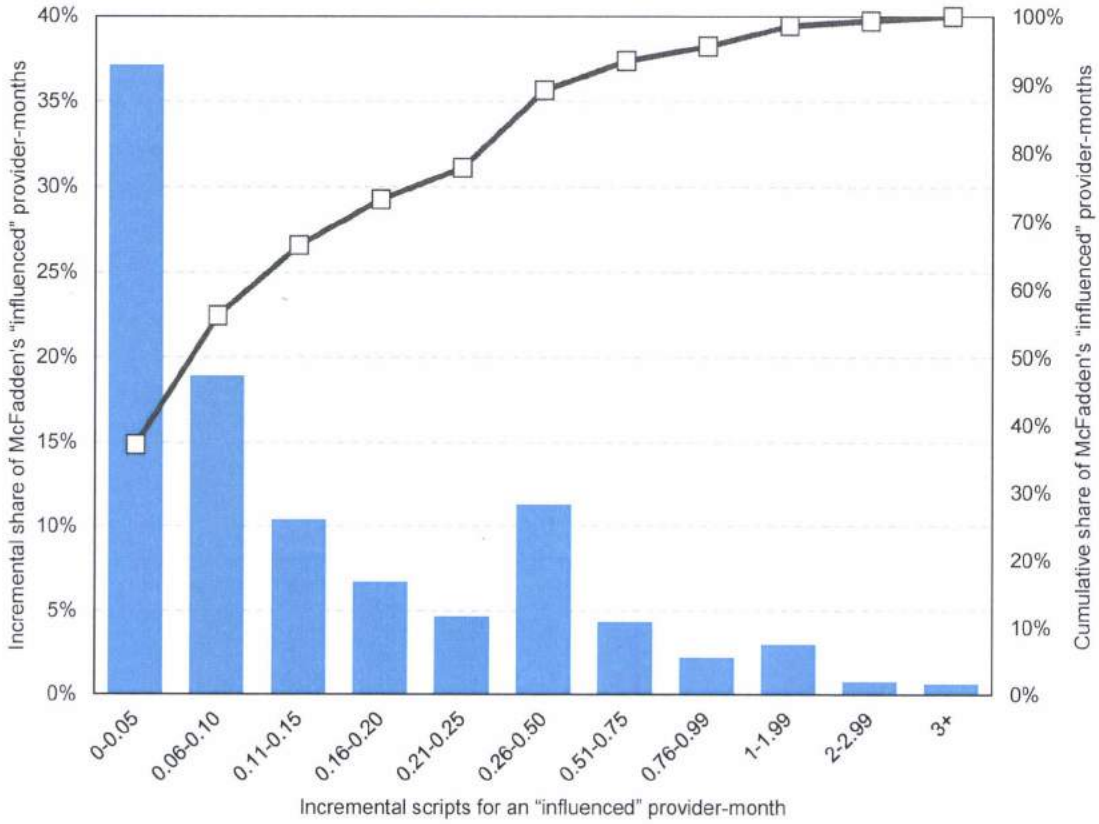
with the concept of "wear out" from the marketing literature.[178] Thus, the diminishing marginal impacts Prof. McFadden's model associates with event attendance are consistent with the results one would observe for promotion.

(102) I begin by noting that the purported impact of alleged kickbacks measured by Prof. McFadden's model is extremely small. Figure 10 below shows the distribution of estimated incremental prescriptions Prof. McFadden's purports to measure across all flagged doctor-month observations (with prescribing). As shown in Figure 10, for approximately 96% of the doctor-month observations for which Prof. McFadden concludes that Novartis's challenged conduct influenced prescriptions, the purported impact was less than 1 incremental new prescription.[179] Indeed, for approximately 78% of those purportedly influenced doctor-month observations, the impact was less than 0.25 new prescriptions. Hence, according to Prof. McFadden's own model, the impact of the alleged kickbacks for any particular doctor-month was extremely small.

[178] Margaret H. Blair, "An Empirical Investigation of Advertising Wearin and Wearout," Journal of Advertising Research, 40(6), (Dec. 2000), pp. 95-100. *See also* Gerard J. Tellis, "Generalizations about Advertising Effectiveness in Markets," Journal of Advertising Research, Vol. 49, No. 2, (June 2009), www.journalofadvertisingresearch.com/content/49/2/240.

[179] Prof. McFadden's model does not require the estimated incremental new prescriptions to be whole numbers. However, because doctors cannot prescribe fractions of prescriptions, it is unreasonable to conclude that a doctor was influenced by alleged kickbacks during a given month in which Prof. McFadden's model finds less than 1 incremental new prescription. Limiting Prof. McFadden's damages calculations to observations for which his model estimates at least 1 incremental new prescription would reduce his baseline damages from $513.6 million to $76.0 million. Moreover, only 8% of the doctors that Prof. McFadden's model finds were influenced by alleged kickbacks have at least 1 month with at least 1 incremental new prescription.

Figure 10: Incremental impact of alleged kickbacks as measured by Prof. McFadden's model



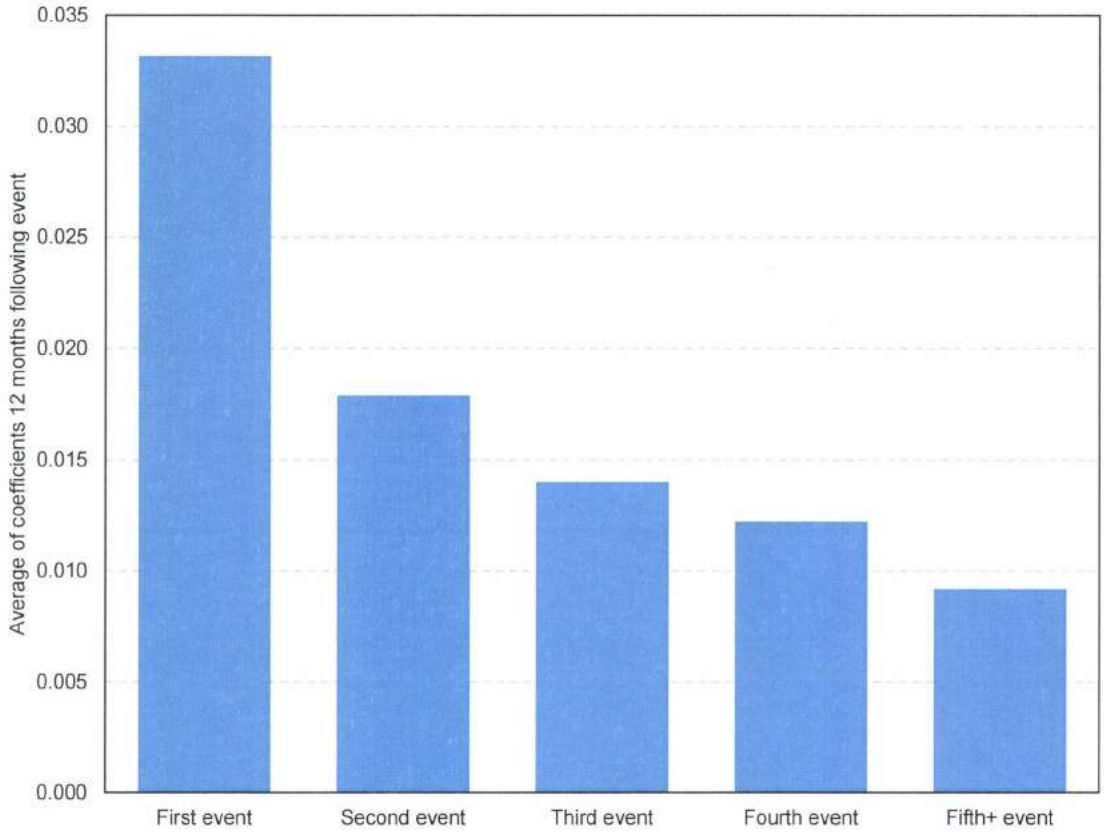
Source: Concerto event data; IMS Health.

(103) When I extend Prof. McFadden's model to incorporate all roundtable and speaker event attendance—not just those flagged as kickbacks—the results demonstrate a clear pattern of diminishing marginal impacts, consistent with promotional wear out. Figure 11 below shows the incremental impact on Diovan HCT prescribing I measure for each subsequent attendance within six months.[180] As shown in Figure 11, the estimated average impact coefficient on Diovan HCT prescribing of the first event attendance within six months is 0.033.[181] The average impact coefficient of subsequent event attendance within six months falls to 0.018 for the second attendance, 0.014 for the third attendance, 0.012 for the fourth attendance, and 0.009 for the fifth or more attendance. I obtain similar results for other subject drugs.

[180] The attendances are defined within a six-month window. However, consistent with Prof. McFadden, I test for impact in the twelve months following these attendances.

[181] Because Prof. McFadden's model involves non-linear transformations, the impact coefficients do not equate to incremental prescriptions. That is, an impact coefficient of 0.033 does not equate to 0.033 prescriptions.

Figure 11: Effect of repeat speaker/roundtable event attendances within last six months on Diovan HCT prescribing



Source: Concerto event data; IMS Health.

(104) The pattern of diminishing marginal impact for repeated attendance of events is also consistent with Novartis's contemporaneous return on investment (ROI) analyses. For example, I note the following characterizations:

> When number of events increase, the marginal ROI for each additional event decreases[182]
>
> Event attendees should be "Tier 1, 2, 3" and "1st time hearing message"[183]

[182] NPCLSV_LIT001213363 at 3386.

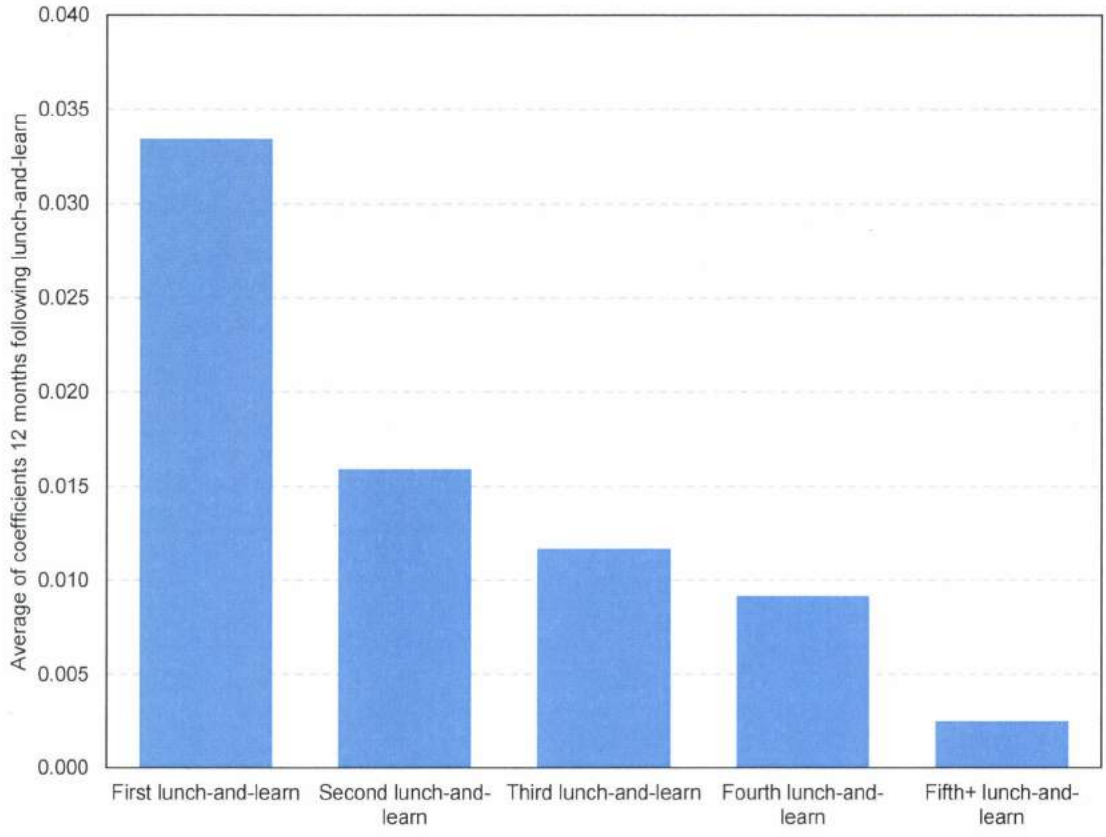
[183] NPCLSV_LIT001643057 at 3070.

> More meetings are not necessarily generating higher ROIs, better contents and execution is more important[184]

(105) To further evaluate whether the pattern of estimated impact coefficients was consistent with promotion, I re-estimate Prof. McFadden's model, but substitute lunch-and-learn events for speaker and roundtable events. Because there is no allegation that lunch-and-learn events constitute kickbacks, they provide a credible benchmark for the pattern of impact coefficients one would expect to observe for promotion. Re-estimating Prof. McFadden's model, I find a similar pattern of diminishing marginal impacts for repeated attendance of lunch-and-learn events. For example, as shown in Figure 12 below, the estimated average impact coefficient of attending a lunch-and-learn event drops from 0.033 to 0.016 to 0.012 to 0.009 to 0.002 as a provider attends each subsequent event within six months. This analysis further supports my opinion that the impacts of speaker and roundtable events that Prof. McFadden purports to identify are consistent with promotion.

[184] NPCLSV_LIT000633432 at 3441.

Figure 12: Effect of repeat lunch-and-learns attendances within last six months on Diovan HCT prescribing



Source: Concerto event data; IMS Health.

VI. Prof. McFadden's model does not test for influence at the doctor level

(106) Prof. McFadden's assertion that his model "serves to identify whether and, if so, when kickbacks increased prescription rates by doctor, drug, and month" is a gross mischaracterization.[185] Even if Prof. McFadden's model reliably measured aggregate influence (which I explain below it does not), it does nothing to test influence at the doctor or doctor-month level. To the contrary, Prof. McFadden imposes the same impact coefficients on all doctor-month observations flagged for alleged kickbacks. In other words, Prof. McFadden's model imposes an assumption that all flagged doctor-month observations were influenced in exactly the same way for a given drug and pattern of alleged kickbacks.

(107) To illustrate Prof. McFadden's mischaracterization, consider the 5% of doctors where Prof. McFadden concludes there was no influence of alleged kickbacks.[186] For the high-volume subject drugs—including Diovan, Diovan HCT, Exforge, Lotrel, and Tekturna—those no-influence observations only arise because those doctors wrote no prescriptions for subject drugs during those months. In other words, for the high-volume drugs, which represent more than 95% of his alleged damages, Prof. McFadden concludes that every flagged doctor-month observation with prescribing was influenced by alleged kickbacks. This is a wholly unreasonable result that demonstrates that Prof. McFadden is not testing for influence of alleged kickbacks at the doctor or doctor-month level.[187]

(108) To test for influence at the doctor level, I re-estimate Prof. McFadden's model, but allow the impact of the alleged kickbacks to vary across doctors.[188] Figure 13 below shows the distribution of estimated doctor-specific impact coefficients for Diovan HCT. As shown in Figure 13, the distribution of coefficients is nearly symmetric, albeit centered slightly to the right of zero. These results are consistent with the small aggregate impact found for Diovan HCT by Prof. McFadden's model. However, whereas Prof. McFadden's model imposes an assumption that all doctors (including

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[185] McFadden Report, ¶ 23.

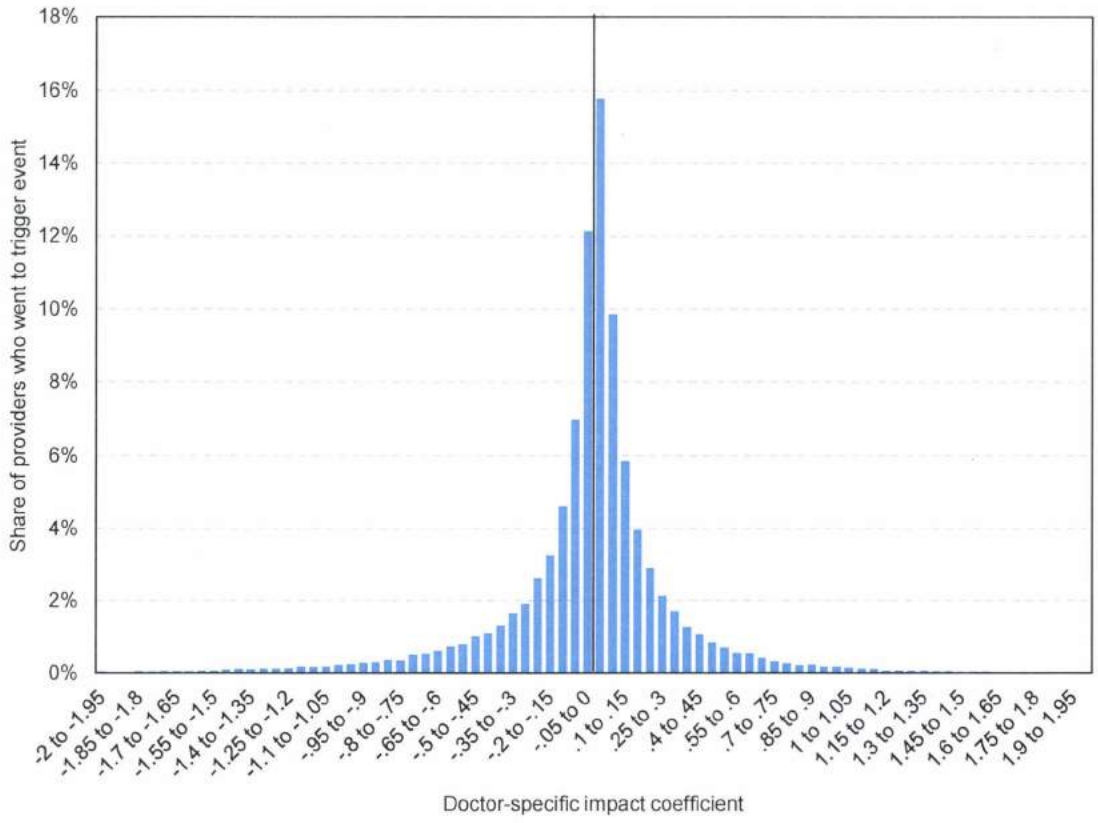
[186] McFadden Report, ¶ 59.

[187] For Exforge HCT, Starlix, Tekturna HCT, and Valturna, Prof. McFadden also concludes that some flagged doctor-month observations were not influenced by alleged kickbacks because those doctors only prescribed subject drugs in months with net negative impact coefficients.

[188] Specifically, I allow the impact of alleged kickbacks to vary across doctors in the same way that Prof. McFadden allows the impact of alleged kickbacks to vary across the preceding twelve months. However, because it is computationally infeasible to allow the impact to vary across both doctors and months, I instead estimate an average impact across time, but allow for doctor-specific impacts. In light of the fact that his damages depend critically on a finding of influence at the doctor (and month) level, it is curious that Prof. McFadden's model focuses on modeling the structure of the lagged impact of the alleged kickbacks but ignores the doctor-specific impacts. Nevertheless, before adding doctor-specific impacts, I confirmed that I generally obtain average lagged impacts that are consistent with Prof. McFadden's original model. The difference between the average of Prof. McFadden's lagged impact coefficients and the single aggregated impact coefficient was less than 2% for all subject drugs where Prof. McFadden's model finds aggregate influence, except for Exforge HCT, Tekamlo, Tekturna HCT, and Valturna. However, as I explain in section VII.A, correcting for confounding factors, these drugs also would not pass Prof. McFadden's test for aggregate influence.

those with negative average impact coefficients in Figure 13) were influenced during flagged months by the same aggregate impact coefficients, these results allow me to test for influence at the doctor level.

Figure 13: Distribution of doctor-specific impact coefficients for Diovan HCT

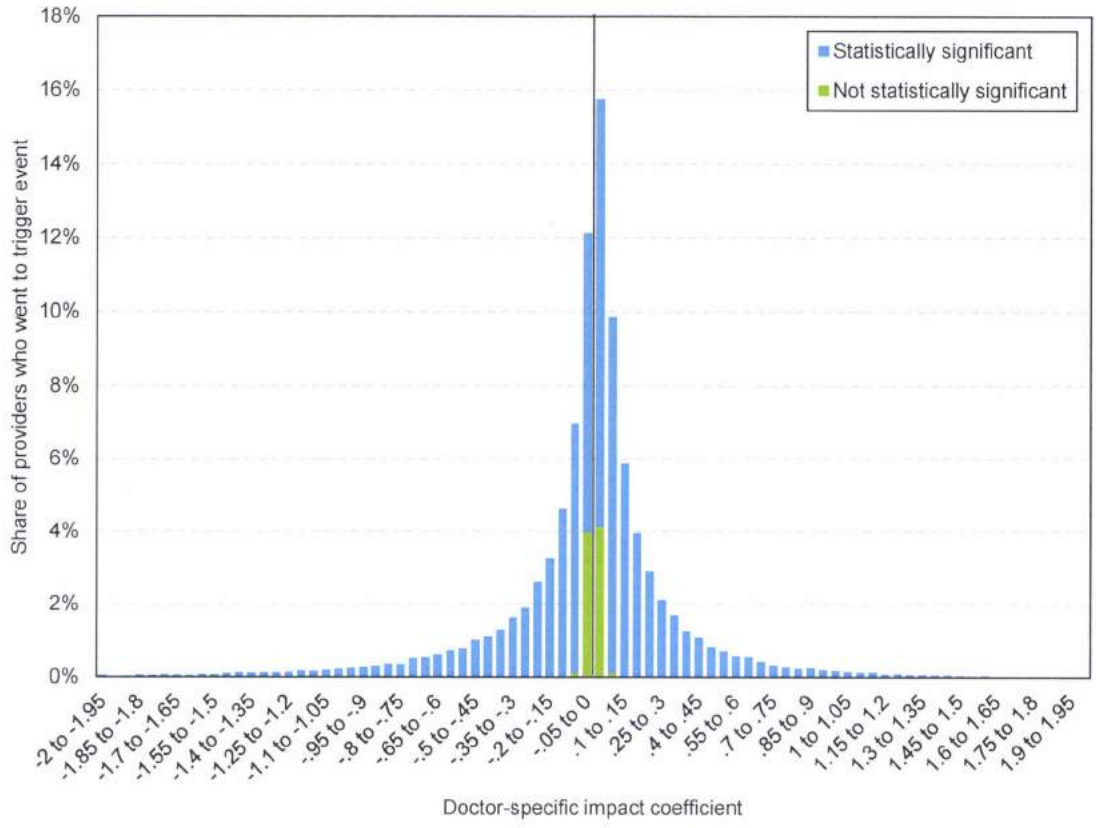


Source: Concerto event data; IMS Health.

(109) I next test each doctor-specific impact coefficient to determine whether it is statistically significant at the 5% level.[189] Figure 14 below shows the distribution of statistically significant and insignificant doctor-specific impact coefficients for Diovan HCT. For Diovan HCT, approximately 8% of the doctors have impact coefficients that are not statistically significant. For those doctors there is no evidence that the alleged conduct influenced their prescribing one way or the other.

[189] I conservatively apply a 5% level in my test of statistical significance. That is, using Prof. McFadden's 0.5% level, even more impact coefficients would not be statistically significant.

Figure 14: Distribution of doctor-specific impact coefficients for Diovan HCT with statistical significance



Source: Concerto event data; IMS Health.

(110) Across all subject drugs, I find that, for approximately 57% of the flagged doctors, the estimated impact coefficient was either negative or not statistically significant (at the 5% level). In other words, simply testing for doctor-specific impact demonstrates that there is no evidence that alleged kickbacks caused at least 57% of flagged doctors to increase their prescribing of subject drugs. Hence, at a minimum, prescriptions written by those doctors should be excluded from Prof. McFadden's damages calculations. Doing so, I reduce Prof. McFadden's baseline damages calculations from $513.6 million to $283.1 million. However, as I explain in section VII.A, even this remaining amount is not a reliable measure of damages because the distribution of doctor-specific impacts is consistent with variation associated with numerous confounding factors omitted from Prof. McFadden's model (among other reasons).

VII. Prof. McFadden's regression model is unreliable

(111) Even for purposes of testing aggregate influence, Prof. McFadden's model suffers from two fundamental flaws that render his results unreliable. First, Prof. McFadden's model fails to account for numerous factors, such as non-challenged marketing to doctors and prescriptions of other antihypertension (or antidiabetic) drugs, which confound his estimates of the impact of the alleged kickbacks on prescribing of subject drugs. Indeed, simply including variables that measure detailing, sampling, and non-challenged events as well as doctors' prescribing of competing non-Novartis drugs, reduces the estimated impact of the alleged kickbacks by more than 50%. Moreover, adding the additional variables causes four subject drugs—Exforge HCT, Tekturna HCT, Valturna, and Starlix—to fail Prof. McFadden's test of causation. Hence, Prof. McFadden would have concluded that there was no causation for these four drugs had he controlled for these factors, and he would have excluded them from his damages calculations as he does for Tekamlo and Lotrel after generic entry. Prof. McFadden's model also omits numerous other confounding factors that are known to influence doctors' prescribing, but for which data are not available.

(112) Second, Prof. McFadden's model fails to account for significant serial correlation in prescribing, which causes him to overstate the statistical significance of his conclusions. When I use a standard procedure to correct Prof. McFadden's model for serial correlation, even without including the additional confounding factors, the model results for the same four subject drugs—Exforge HCT, Tekturna HCT, Valturna, and Starlix—no longer meet Prof. McFadden's own test of causation.

(113) In this section, I explain these fundamental flaws in Prof. McFadden's model.

VII.A. Prof. McFadden's regression model fails to control for confounding factors

(114) Prof. McFadden's model fails to control for confounding factors that are known to impact prescribing. Omitting such factors means that Prof. McFadden's estimated impact coefficients are biased, in violation of a standard assumption of regression analysis.[190] Specifically, when the correlation between the alleged kickback variables and the omitted variables is positive—as is the case for non-challenged promotion, for example—the impact coefficients are biased upward, which causes Prof. McFadden to over-estimate the impact of the alleged kickbacks.[191]

(115) Prof. McFadden is clearly aware of the problem of omitted variables because he acknowledges that factors other than the alleged kickbacks "could contribute to differences in levels of prescription rates

[190] *See, e.g.*, James H. Stock and Mark W. Watson, "Introduction to Econometrics," Pearson, 3rd ed. update (2015), p. 720.

[191] For an illustration in linear regression, *see, e.g.*, James H. Stock and Mark W. Watson, "Introduction to Econometrics," Pearson, 3rd ed. update (2015), pp. 185–186.

between doctors…"[192] However, he attempts to control for such confounding factors only by including doctor-specific and time-period-specific fixed effects.[193] While such doctor- and time-specific fixed effects would control for potential differences between doctors that do not vary over time (e.g., specialty) and differences between time periods that do not vary across doctors (e.g., entry of a new antihypertension drug competitor), the fixed effects in Prof. McFadden's model fail to control for factors that vary over time for a given doctor.[194] While there are many potential factors that might vary over time for a given doctor, the most obvious factors are (1) doctor-specific promotion, such as detailing, sampling and other non-challenged events and (2) prescribing of competing, non-Novartis drugs.

(116) As I explained in section V.A, doctor-specific promotion such as detailing, sampling, and non-challenged events is ubiquitous and known to influence prescribing. To illustrate this influence, consider, Figure 15 below, which illustrates Diovan detailing and prescribing for a particular doctor. As shown in Figure 15, for this doctor, there is a relatively high degree of correlation between Diovan detailing and prescribing.[195] There are many doctors (and drugs) for whom there is a high degree of correlation between detailing and prescribing and many others for whom there is not.[196] However, because Prof. McFadden's model does not control for variation over time in such doctor-specific promotion, it ignores the possibility that any increased prescribing was caused, at least in part, by increased detailing.

[192] McFadden Report, ¶ 37.

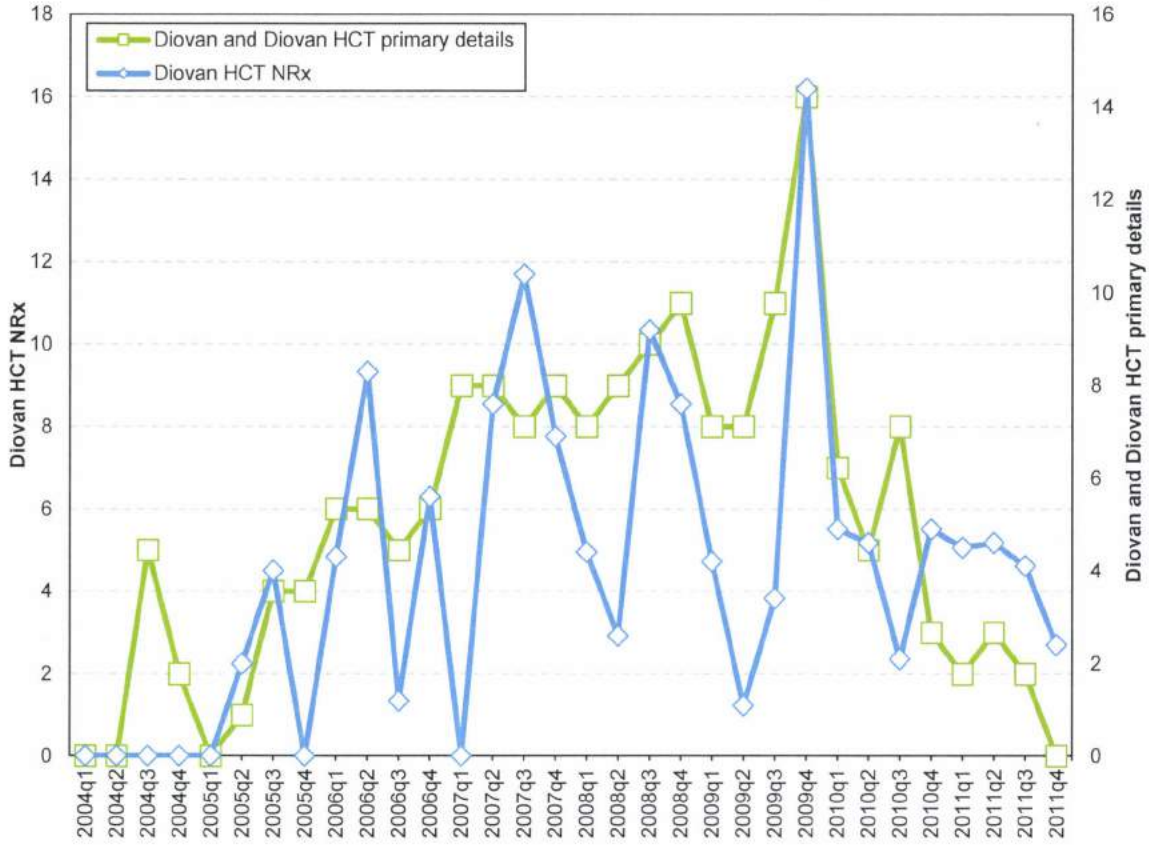
[193] McFadden Report, ¶ 43.

[194] Jushan Bai, "Panel Data Models With Interactive Fixed Effects;" Econometrica – Journal of Economic Society: Vol. 77, Issue 4 (2009), pp. 1229–1279.

[195] The correlation coefficient between Diovan detailing and prescribing for this doctor is 0.63.

[196] I do not assert that the degree of correlation shown in Figure 15 is representative of all doctors and subject drugs. To the contrary, I have specifically selected a doctor and drug to illustrate a relatively high degree of correlation between detailing and prescribing.

Figure 15: Diovan prescribing and detailing for a particular doctor

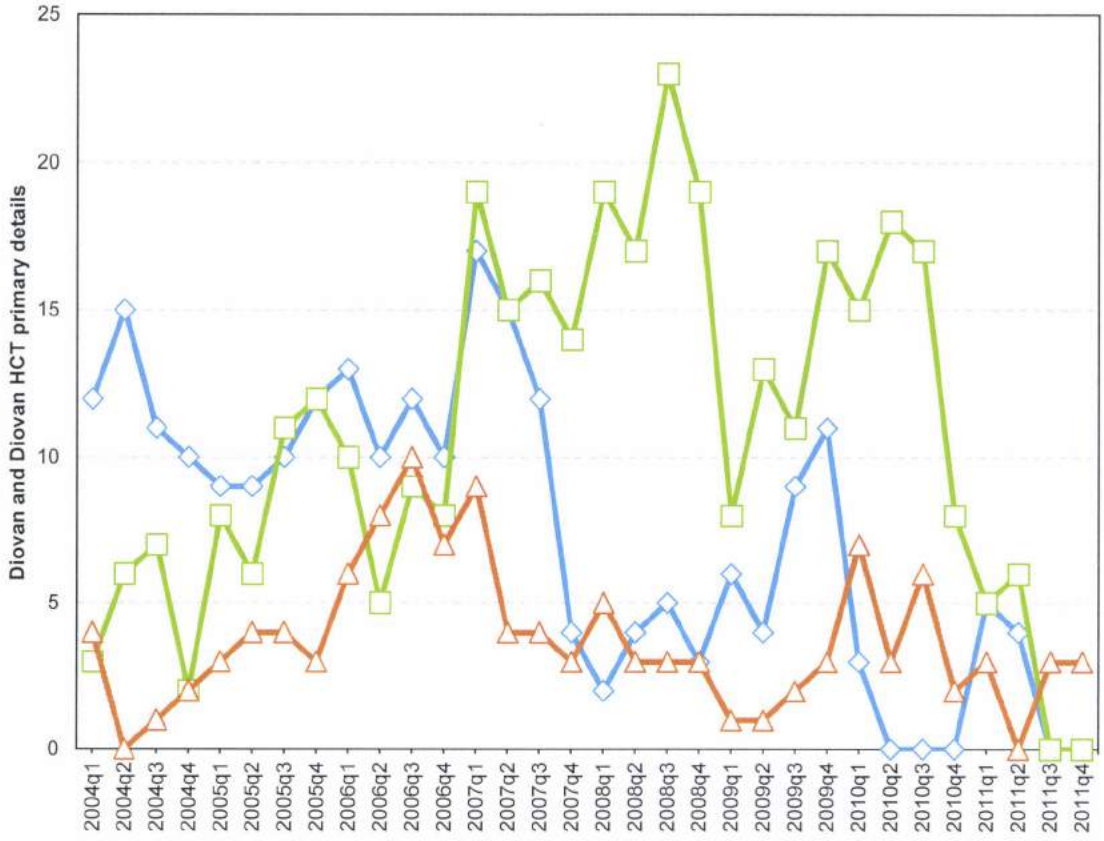


Source: IMS Health; Novartis details data

Note: Details and prescribing shown for Nov ID 2353833

(117) Not only does such promotion vary over time for a given doctor, the pattern of promotion varies across doctors. Consider Figure 16 below, which illustrates Diovan detailing for three different doctors over time. While this figure represents only three examples for a single subject drug, it illustrates the general point that detailing varies significantly over time for a given doctor. Indeed, the pattern of promotion to any given doctor is effectively unique to that doctor. Hence, the fixed effects in Prof. McFadden's model do not control for such promotion.

Figure 16: Quarterly Diovan detailing visits for three providers



Source: Novartis details data.

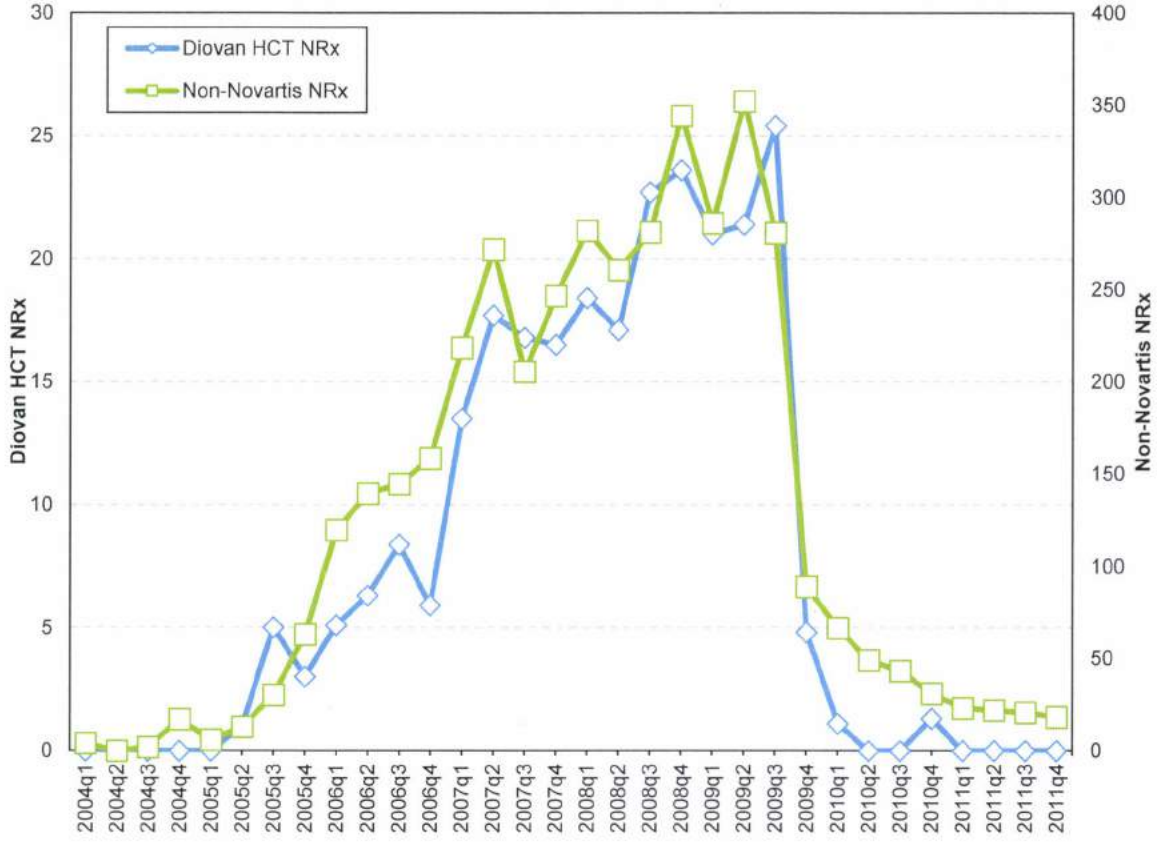
Note: Details shown for providers with Nov IDs of: 850082, 719111, 139483.

(118) The fixed effects in Prof. McFadden's model also do not control for changes in a given doctor's practice over time. For example, a doctor's practice may grow over time causing them to prescribe more antihypertension (or antidiabetes) drugs, not just Novartis's subject drugs. Similarly, the mix of patients seen by a given doctor may change over time causing them to prescribe more (or less) antihypertension (or antidiabetes) drugs, not just Novartis's subject drugs. Hence, one effective proxy for relevant changes over time in a doctor's practice is the number of competing, non-Novartis antihypertension (or antidiabetes) prescriptions. Consider Figure 17 below, which illustrates Diovan HCT prescribing and prescribing of non-Novartis antihypertension drugs for a particular doctor. As shown in Figure 17, for this doctor, there is a high degree of correlation between such prescribing.[197] There are many doctors for whom there is a high degree of correlation between prescribing of subject drugs and prescribing of non-Novartis antihypertension drugs and many others for whom there is

[197] The correlation coefficient between Diovan HCT prescribing and prescribing of non-Novartis antihypertension drugs for this doctor is 0.97.

not.[198] However, because Prof. McFadden's model does not control for variation in such doctor-specific prescribing of non-Novartis antihypertension drugs, it ignores the possibility that any increased prescribing was caused, at least in part, by changes in the doctors' practices.

Figure 17: Diovan HCT and non-Novartis antihypertensive prescribing for a particular doctor



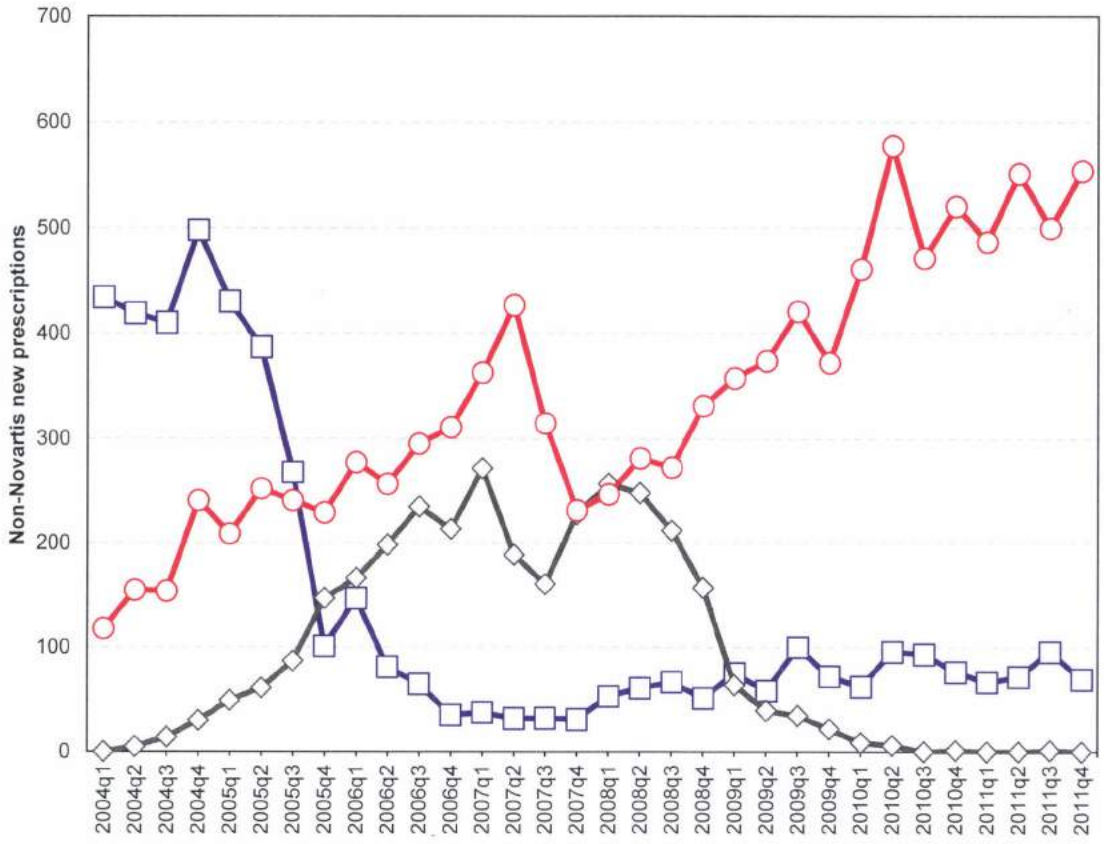
Source: IMS Health.

Note: Prescribing shown for Nov ID 1589498

(119) Not only does non-Novartis antihypertension prescribing vary over time for a given doctor, the pattern of such prescribing varies across doctors. Consider Figure 18 below, which illustrates non-Novartis antihypertension prescribing for three different doctors over time. While these patterns represent only three examples, they illustrate the general point that doctors' practices change over time in ways that Prof. McFadden's fixed effects fail to control for.

[198] I do not assert that the degree of correlation shown in Figure 17 is representative of all doctors and subject drugs. To the contrary, I have specifically selected a doctor and drug to illustrate a high degree of correlation between subject drug prescribing and prescribing of non-Novartis antihypertension drugs.

Figure 18: Quarterly prescriptions of non-Novartis antihypertension drugs for three providers



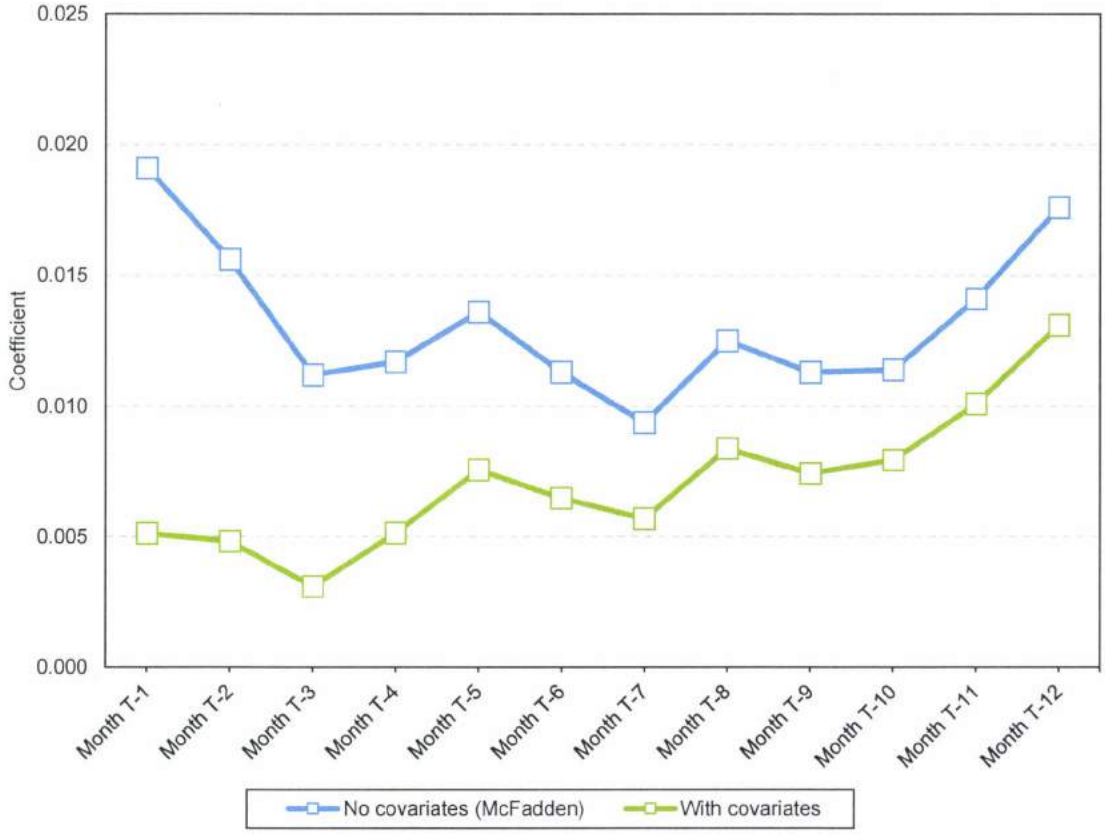
Source: IMS Health.

Note: Prescribing shown for providers with Nov IDs of: 1987273, 2131850, 377108.

(120) Prof. McFadden's omission of confounding factors has a dramatic impact on the results of his model. Simply including variables that measure detailing, sampling, and non-challenged events as well as doctors' prescribing of competing drugs, I demonstrate that Prof. McFadden's results overstate the purported impact of Novartis's challenged conduct by a factor of 2.

(121) For example, Figure 19 below shows the estimated coefficients on the 12 lagged impact variables from Prof. McFadden's model for Diovan HCT, as well as the estimated coefficients from a version of Prof. McFadden's model that also includes lagged measures of detailing, sampling, non-challenged promotion and doctors' prescribing of non-Novartis antihypertension drugs. As shown in Figure 19, including the additional promotion and prescribing variables reduces the estimated impact coefficients by 25% to 75%.

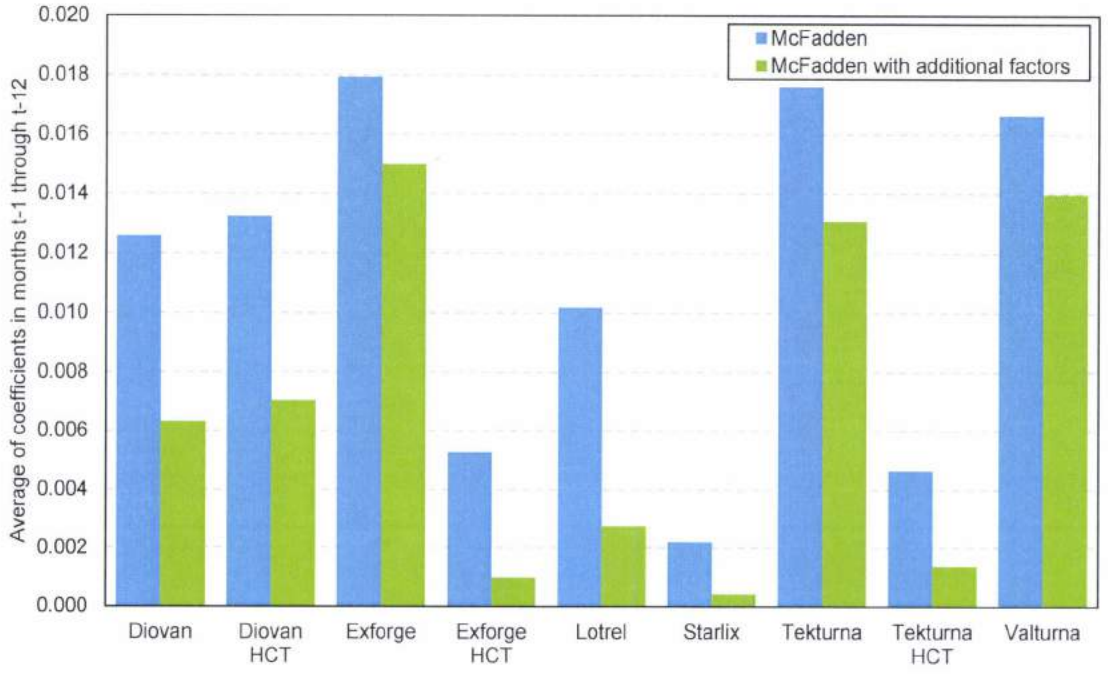
Figure 19: Estimated Diovan HCT impact coefficients estimated by Prof. McFadden and correcting for some confounding factors



Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

(122) Figure 20 below shows the comparable results for each of the subject drugs, averaging across the lagged coefficients. Similar to the results for Diovan HCT, including the additional promotion and prescribing variables for each drug reduces the average impact coefficients by as much as 81%.

Figure 20: Estimated average impact coefficients estimated by Prof. McFadden and correcting for some confounding factors



Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

(123) Figure 21 below provides a summary of the impact of including doctor-specific promotion and prescribing variables in Prof. McFadden's model for each subject drug. Although the impact of including these confounding factors varies across the subject drugs, overall, the estimated impact of the alleged kickbacks is reduced by more than 50%.[199] Moreover, including these additional variables causes four subject drugs—Exforge HCT, Tekturna HCT, Valturna, and Starlix—to fail Prof. McFadden's own tests of overall statistical significance. Hence, Prof. McFadden would have concluded that there was no causation for these four drugs and excluded them from his damages calculations as he does for Tekamlo and Lotrel after generic entry.

[199] See McFadden Report, Table 6.

Figure 21: Prof. McFadden's t-test of average incremental new prescriptions correcting for some confounding factors

Drug	Avg. total incremental new Rx across simulations	Standard error	T-statistic	Is there < 0.5% chance that the incremental is non-positive?
Diovan	121,063	2,128	57	Yes
Diovan HCT	155,755	2,208	71	Yes
Exforge	36,633	680	54	Yes
Exforge HCT	479	218	2	No
Starlix	1,296	609	2	No
Tekamlo	-143	94	-2	No
Tekturna	20,099	588	34	Yes
Tekturna HCT	842	305	3	No
Valturna	795	292	3	No
Lotrel: Before Generic	37,626	2,189	17	Yes
Lotrel: After Generic	3,556	553	6	Yes

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

(124) Prof. McFadden's model also omits numerous other factors that are known to influence doctor prescribing, but for which data are not readily available. For example, third-party payors use formularies and preferred drug lists to influence doctors' prescribing. Similarly, other manufacturers' marketing should reduce doctors' prescribing of Novartis's subject drugs. Hence, much of the impact that Prof. McFadden's model purports to measure is likely caused by other important, but omitted variables.

(125) To demonstrate the overall unreliability of Prof. McFadden's model, I perform a "placebo" or "false positive" test in which I use his model to estimate the impact of the alleged kickbacks on doctors' prescribing of non-Novartis antihypertension drugs. If Prof. McFadden's model reliably tested for causation, I should not find that Novartis's alleged kickbacks influenced prescribing of non-Novartis antihypertension drugs. However, as shown in Figure 23, I find that Prof. McFadden's model would conclude that Novartis's alleged kickbacks caused increased prescribing of non-Novartis antihypertension drugs. This unexpected result further confirms that Prof. McFadden's model does not reliably test for causation.

Figure 22: Prof. McFadden's t-test of average incremental new prescriptions of non-Novartis antihypertension drugs

Drug	Avg. total incremental new Rx across simulations	Standard error	T-statistic	Is there < 0.5% chance that the incremental is non-positive?
Non-Novartis antihypertension drugs	1,939,729	8,609	225	Yes

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

VII.B. Prof. McFadden's regression model fails to control for serial correlation

(126) Prof. McFadden's model fails to account for significant serial correlation in prescribing, which causes him to overstate the statistical significance of his conclusions. Serial correlation means that the regression "errors" are correlated over time, in violation of a standard assumption of regression analysis.[200] Specifically, in the presence of (positive) serial correlation, the standard errors of the parameter estimates are biased toward zero, which causes the statistical significance of the regression parameters to be overstated.[201] Serial correlation, by itself, does not cause the estimated coefficients to be biased. However, the downward bias in the standard errors biases Prof. McFadden's tests of statistical significance toward finding aggregate influence.

(127) Serial correlation is quite common in time series and panel data, such as Prof. McFadden's data regarding doctors' prescribing patterns over time.[202] In the context of non-linear models, a standard practice is to employ a "cluster" procedure that allows for (but does not impose) any arbitrary form of serial correlation.[203] In our case, the cluster procedure allows for the regression errors to be serially correlated for a given doctor and produces "robust" standard errors that correct for any serial correlation that is present.[204] Hence, if there is no serial correlation, the "robust" standard errors produced by the cluster procedure will be similar to the standard errors estimated without the cluster procedure. However, if there is serial correlation, the robust standard errors will differ from the standard errors estimated without the cluster procedure.

(128) I re-estimate Prof. McFadden's model allowing for serial correlation using the standard cluster procedure described above. As shown in Figure 23 below, the presence of uncorrected serial correlation causes Prof. McFadden to overstate the statistical significance of his regression results even without including the additional confounding factors I previously discussed. In particular, correcting for serial correlation increases the standard errors on the estimated incremental prescriptions for each subject drug by as much as 2 to 5 times. For example, for Diovan, the standard error increases from 2,034 to 9,079, an increase of approximately 4.5 times (i.e., 450%). Similarly, for Diovan HCT, the standard error increases from 2,092 to 11,028, an increase of approximately 5.3 times (i.e., 530%).[205] As shown in Figure 23, correcting for serial correlation causes the same four

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[200] *See*, e.g., James H. Stock and Mark W. Watson, "Introduction to Econometrics," Pearson, 3rd ed. update (2015) p. 720.

[201] Jeffrey M. Wooldridge, *Introductory Econometrics: A Modern Approach*, Cengage Learning, 6th edition, 2015, pp. 373–374.

A. Colin Cameron and Pravin K. Trivedi, Regression Analysis of Count Data, 2nd edition, Cambridge University Press, 2013.

[202] Jeffrey M. Wooldridge, "Introductory Econometrics: A Modern Approach," Cengage Learning, 6th ed. (2015) p. 321.

[203] Jeffrey M. Wooldridge, "Distribution-Free Estimation of Some Nonlinear Panel Data Models," Journal of Econometrics: Vol. 90 1999(90): pp. 77–97.

[204] The standard cluster procedure I use also corrects for heteroscedasticity of the regression errors.

[205] See McFadden Report, Table 6.

drugs—Exforge HCT, Tekturna HCT, Valturna, and Starlix—to fail Prof. McFadden's own test of overall statistical significance.

Figure 23: Prof. McFadden's t-test of average incremental new prescriptions corrected for serial correlation

Drug	Avg. total incremental new Rx across simulations	Standard error	T-statistic	Is there < 0.5% chance that the incremental is non-positive?
Diovan	243,936	9,079	27	Yes
Diovan HCT	281,846	11,028	26	Yes
Exforge	43,684	2,567	17	Yes
Exforge HCT	1,043	528	2	No
Starlix	2,738	1,483	2	No
Tekamlo	-185	149	-1	No
Tekturna	26,535	2,355	11	Yes
Tekturna HCT	2,003	781	3	No
Valturna	817	926	1	No
Lotrel: Before Generic	145,781	7,329	20	Yes
Lotrel: After Generic	-4,623	2,607	-2	No

Source: Concerto event data; IMS Health; McFadden Report.

VII.C. Results of correcting Prof. McFadden's regression model

(129) While I am not able to correct all of the flaws in Prof. McFadden's model, as shown in Figure 2, correcting those I can address reduces his damages substantially. Specifically, Figure 24 below shows the results of Prof. McFadden's model when I simultaneously test for doctor-specific impacts and correct for both serial correlation and the omission of some confounding factors.[206] As shown in Figure 24, combining these corrections reduces Prof. McFadden's total damages from $513.6 million to $229.5 million. Moreover, these corrections reduce Prof. McFadden's incremental damages from $22.5 million to $0.8 million.

[206] When I include the additional confounding factors in Prof. McFadden's model, the problem of serial correlation is effectively eliminated (i.e., the cluster procedure does not significantly increase the standard errors of the parameter estimates for most drugs). This result is not surprising as serial correlation can be an indication of omitted variables. Hence, the presence of significant serial correlation in Prof. McFadden's model, as well as the lack of serial correlation in the corrected model, further supports my inclusion of the additional confounding factors. *See* Studenmund, A.H., Johnson, B.K., 2016. Using Econometrics: A Practical Guide. Pearson, 307-313.

Figure 24: Prof. McFadden's damages (in millions) after corrections to his model

Scenario	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8

Source: Concerto event data; Government claims data; IMS Health; McFadden Report; McFadden supplemental materials; Novartis details data; Novartis samples data.

VIII. Prof. McFadden's regression model is corrupted by numerous errors in the input data on which he relies

VIII.A. Dr. Goldberg overstates event attendances that match his purported kickback criteria

(130) Prof. McFadden's model is corrupted by two significant errors in the construction of the input data provided by Dr. Goldberg. First, Dr. Goldberg erroneously includes numerous events that are categorized as roundtable events in Novartis's data but appear to have been lunch-and-learn events taking place at the doctor's offices.[207] This distinction is important because the government does not challenge lunch-and-learn events and Dr. Goldberg excludes numerous lunch-and-learn events that were categorized incorrectly in the Novartis data as roundtable events.[208] Nevertheless, Dr. Goldberg includes approximately 75,000 (about 21% of the total 363,000 events) additional lunch-and-learn events in his analysis of challenged conduct. I identify these additional lunch-and-learns as events where the location implies either a doctor's office or a venue unlikely to host an event (such as Dunkin Donuts, implying that food was brought to a provider's office).[209]

(131) Second, Dr. Goldberg erroneously double counts the cost of meals for numerous multiproduct events, which causes him to overstate the frequency of events with per-participant spending on meals that exceeds $125. Dr. Goldberg determines per-participant spending on meals by aggregating all meal spend associated with an event and then dividing by the number of participants. For multiproduct events, Novartis's Concerto data reports meal spending separately for each product featured at the event. However, some sales representatives appear to have entered the total amount of meal spending for every product. Consequently, in those instances, Dr. Goldberg's methodology erroneously double counts the total amount of meal spending, which causes him to overstate the frequency of events with per-participant spending that exceeds $125.

(132) The erroneous inclusion of additional lunch-and-learn events and double counting of meal spending at multiproduct events causes Dr. Goldberg to significantly overstate the instances where doctors allegedly received kickbacks. Consequently, even if Prof. McFadden's model were otherwise reliable, it would significantly overstate the impact of the alleged kickbacks on prescribing of Novartis's subject drugs.

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[207] As I explain in section IV.B, the distinction between roundtable events and lunch-and-learn events is that the former take place outside the doctor's office whereas the latter take place at the doctor's office.

[208] Specifically, Dr. Goldberg excludes events that were categorized as roundtable events in the Novartis data but had event titles describing lunch-and-learn events. Goldberg Report, p. 13.

[209] Specifically, I identify additional lunch-and-learns as events with an "event type" of "REF-ROUNDTABLE" and either a (1) "location_type" of "OFFICE" or (2) "location" containing select terms. For additional detail, see Appendix F.

(133) I re-calculate Prof. McFadden's damages, but exclude the erroneous lunch-and-learn events and correct the per-participant spending on meals at multiproduct events. As shown in Figure 25 below, the damages found by Prof. McFadden's model are reduced about 13% from $513.6 million to $445.8 million. Similarly, using a version of Prof. McFadden's model that corrects for doctor-specific effects, serial correlation, and some confounding factors, the damages (as defined by Prof. McFadden) are reduced about 12% from $229.5 million to $201.8 million.

Figure 25: Summary of Prof. McFadden's damages (in millions) after correcting his identification of lunch-and-learn events and calculation of meal spending at multiproduct events

Adjustment to challenged events	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Remove additional lunch-and-learns (L&Ls) and correct meal spending	$445.8	$19.9	$201.8	$1.3

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

VIII.B. Dr. Goldberg incorrectly includes pre-2010 events for Diovan, Exforge, and Tekturna

(134) Dr. Goldberg's analysis also includes pre-2010 events for Diovan, Exforge, and Tekturna, which I have been instructed is not appropriate. Based upon that instruction, these inclusions also cause Dr. Goldberg to significantly overstate the instances where doctors allegedly received kickbacks and, consequently, cause Prof. McFadden's model to overstate damages.

(135) As I noted in section II, in his initial report, Prof. McFadden provides a sensitivity analysis in which he excludes pre-2010 promotional events for Diovan, Exforge, and Tekturna. Although Prof. McFadden does not provide a corresponding sensitivity for his supplemental materials, it is straightforward to extend Prof. McFadden's pre-2010 scenario to his expanded Medicaid methodology.[210] As shown in Figure 26, under that scenario, damages are reduced from $513.6 million to $189.8 million, a reduction of 63%. Similarly, using a version of Prof. McFadden's model that corrects for doctor-specific effects, serial correlation, and some confounding factors, the damages (as defined by Prof. McFadden) are reduced about 64% from $229.5 million to $83.7 million.

[210] At the instruction of counsel, I also adjust Prof. McFadden's pre-2010 scenario by excluding multiproduct events for all products when one of the products featured is covered by the prior settlement. For example, for a pre-2010 event that featured both Diovan and Lotrel, I exclude the event for calculations pertaining to both Diovan and Lotrel. Prof. McFadden only excludes the events for calculations pertaining to the product covered by the prior settlement.

Figure 26: Summary of Prof. McFadden's damages (in millions) after removing pre-2010 DET events

Adjustment to challenged events	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Remove pre-2010 Diovan, Exforge, and Tekturna (DET) events	$189.8	$4.9	$83.7	$0.5

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

VIII.C. Dr. Goldberg incorrectly includes pre-2010 prescriptions and events for Diovan HCT, Exforge HCT, and Tekturna HCT

(136) Dr. Goldberg's analysis also includes pre-2010 prescriptions and events for Diovan HCT, Exforge HCT, and Tekturna HCT, which I have been instructed is not appropriate. Based upon that instruction, these inclusions also cause Dr. Goldberg to significantly overstate the instances where doctors allegedly received kickbacks concerning Novartis's subject drugs and, consequently, cause Prof. McFadden's model to overstate damages.

(137) In addition to my instruction from counsel, I note that Novartis did not generally distinguish between Diovan and Diovan HCT events, Exforge and Exforge HCT events, and Tekturna and Tekturna HCT events in the event data relied upon by Dr. Goldberg and Prof. McFadden.[211] Indeed, Dr. Goldberg goes to some length in attempting to identify which events were for HCT versions of these drugs.[212] Hence, my instruction from counsel to also exclude Diovan HCT, Exforge HCT, and Tekturna HCT events and prescriptions is consistent with Novartis's contemporaneous documentation.

(138) I re-calculate Prof. McFadden's damages but exclude pre-2010 prescriptions for Diovan HCT, Exforge HCT, and Tekturna HCT. As shown in Figure 27, Prof. McFadden's damages are reduced 51% from $513.6 million to $252.9 million. Similarly, using a version of Prof. McFadden's model that corrects for doctor-specific effects, serial correlation, and some confounding factors, the damages (as defined by Prof. McFadden) are reduced about 55% from $229.5 million to $102.5 million.

[211] Goldberg Report, fn. 27.

[212] Goldberg Report, fn. 31.

Figure 27: Summary of Prof. McFadden's damages (in millions) after removing pre-2010 DET+HCT prescriptions

Adjustment to challenged claims	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Remove pre-2010 DET+HCT prescriptions	$252.9	$8.3	$102.5	<$0.0

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

(139) I also re-calculate Prof. McFadden's damages, but exclude pre-2010 Diovan HCT, Exforge HCT, and Tekturna HCT prescriptions and promotional events.[213] As shown in Figure 28, Prof. McFadden's damages are reduced 77% from $513.6 million to $119.5 million. Similarly, using a version of Prof. McFadden's model that corrects for doctor-specific effects, serial correlation and some confounding factors, the damages (as defined by Prof. McFadden) are reduced 79% from $229.5 million to $48.4 million.

Figure 28: Summary of Prof. McFadden's damages (in millions) after removing pre-2010 DET+HCT prescriptions and events

Adjustment to challenged claims/events	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Remove pre-2010 DET+HCT prescriptions and events	$119.5	$2.8	$48.4	<$0.0

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

VIII.D. Prof. McFadden's damages calculations incorrectly include claims for managed Medicaid

(140) Based upon his supplemental materials, Prof. McFadden asserts that the government suffered approximately $15.9 million in damages through managed Medicaid programs, with the U.S. Government accounting for approximately $8.7 million and certain state governments accounting for the remaining $7.3 million.[214] However, as I explained in section IV.C.2, the challenged conduct

[213] Here, I also adjust Prof. McFadden's pre-2010 scenario by excluding multiproduct events for all featured products. See fn. 209.

[214] Supplemental McFadden Materials, Table 1.

likely would not have impacted the government through managed Medicaid programs because those programs are administered by private third-party payors (similar to Medicare Part D). Indeed, under managed Medicaid programs, the government typically pays a capitated per-member-per-month rate based upon the expected utilization of the members across all covered drugs (and medical services). In any case, unlike Medicare Part D, Prof. McFadden has not provided any analysis of government impact under managed Medicaid. Hence, there is no evidence that the government suffered any impact under managed Medicaid programs.

(141) As shown in Figure 29 below, when I exclude managed Medicaid claims from Prof. McFadden's calculations, damages are reduced 3% from $513.6 million to $497.7 million. Similarly, using a version of Prof. McFadden's model that corrects for doctor-specific effects, serial correlation, and some confounding factors, the damages (as defined by Prof. McFadden) are reduced approximately 3% from $229.5 million to $222.4 million.

Figure 29: Summary of Prof. McFadden's damages (in millions) after removing managed Medicaid claims

Adjustment to challenged claims	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Remove managed Medicaid claims	$497.7	$21.7	$222.4	$0.7

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

VIII.E. Results of combined corrections to Prof. McFadden's data inputs

(142) Figure 30 below summarizes the results of corrections I make to Prof. McFadden's data inputs. For example, as shown in Figure 30, removing managed Medicaid claims, additional lunch-and-learn events; pre-2010 Diovan, Exforge, and Tekturna events; and pre-2010 Diovan HCT, Exforge HCT, and Tekturna HCT events and prescription claims reduces damages in Prof. McFadden's model by 81% from $513.6 million to $97.0 million. Similarly, removing the same events and prescriptions from a partially corrected version of Prof. McFadden's model reduces damages from $229.5 million to $40.4 million.[215]

[215] I have also been asked by counsel to calculate the number of trigger events, Novartis sales representatives, and doctors that are associated with each of these scenarios. I provide those calculations in Appendix H.

Figure 30: Summary of Prof. McFadden's damages (in millions) after correcting some flaws in his model and data inputs

Adjustment to challenged claims/events[216]	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Remove managed Medicaid (MM) claims	$497.7	$21.7	$222.4	$0.7
Remove MM claims and additional lunch-and-learns (L&Ls) and correct meal spending	$432.1	$19.2	$195.5	$1.2
Remove MM claims, L&Ls, and pre-2010 Diovan, Exforge, and Tekturna (DET) events and correct meal spending	$154.7	$4.0	$69.6	$0.5
Remove MM claims, L&Ls, pre-2010 DET events, and pre-2010 DET+HCT events and prescriptions and correct meal spending	$97.0	$2.3	$40.4	$0.1

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

[216] There is no particular order to the adjustments shown. Should the Court deem it relevant, I can provide any combination of these adjustments.

IX. Prof. McFadden's calculations do not correspond to any reliable measure of economic damages

(143) Prof. McFadden's calculations do not correspond to any reliable measure of economic damages. First, Prof. McFadden's baseline damages calculations are based upon the total prescriptions reimbursed by the government for providers and time periods where he asserts they were influenced by alleged kickbacks (i.e., 8.5 million prescriptions), not the incremental prescriptions purportedly resulting from the challenged conduct (i.e., 381,000 prescriptions). Economic damages should be based upon incremental expenditures the government incurred as a result of the challenged conduct, not the total expenditures.

(144) Second, Prof. McFadden fails to offset damages with the substantial Medicaid and TRICARE rebates received by the government for challenged drug utilization.[217] Even if the government were entitled to recover the total amounts (as opposed to the incremental amounts) reimbursed by governmental programs as Prof. McFadden's assumes, damages should be based upon net government expenditures, not gross expenditures.

(145) Third, Prof. McFadden's damages fail to offset costs that the government would have incurred but-for the challenged conduct. Specifically, Prof. McFadden's damages inappropriately include dispensing fees, which the government would have paid regardless of which antihypertension (or antidiabetic) drug was prescribed. Similarly, Prof. McFadden fails to offset damages with the costs of other drugs that would have been prescribed but-for the challenged conduct.

IX.A. Prof. McFadden fails to account for Medicaid and TRICARE rebates

(146) As I explained in sections IV.C, pharmaceutical manufacturers, including Novartis, pay substantial rebates to Medicaid and TRICARE programs that significantly reduce the government's net expenditures for prescription drugs. However, Prof. McFadden ignores these rebates and inappropriately bases his damages calculations on the government's gross expenditures instead of net expenditures. Hence, Prof. McFadden's damages provide a windfall to the government because they assume that the government is entitled to recover a portion of its expenditures that it has already recovered in the form of rebates.

(147) I correct Prof. McFadden's damages by offsetting his calculations with rebates paid by Novartis to Medicaid and TRICARE programs for challenged drug utilization. Specifically, for each Medicaid or

[217] Rebates for Medicare Part D drug utilization are implicitly included in Prof. McFadden's government impact calculations.

TRICARE prescription included in Prof. McFadden's damages calculations, I offset the government's gross expenditures with the average rebate paid for that drug's utilization in the respective program during the same quarter. The result of this correction is damages based upon the government's net expenditures instead of its gross expenditures.

(148) As shown in Figure 31 below, Prof. McFadden's failure to account for Medicaid and TRICARE rebates significantly inflates his damages calculations. Specifically, accounting Medicaid and TRICARE rebates reduces damages in Prof. McFadden's model by 12% from $513.6 million to $451.3 million. Similarly, accounting for Medicaid and TRICARE rebates from a partially corrected version of Prof. McFadden's model reduces damages by 12% from $229.5 million to $202.2 million.

Figure 31: Summary of Prof. McFadden's damages (in millions) after accounting for Medicaid & TRICARE rebates paid by Novartis

Adjustment to challenged claims	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Offset Medicaid & TRICARE rebates	$451.3	$19.6	$202.2	$0.8

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data; Rebate data.

IX.B. Prof. McFadden fails to account for dispensing fees and but-for prescriptions

(149) Prof. McFadden's damages also fail to offset costs that the government would have incurred but-for the challenged conduct. Specifically, Prof. McFadden's damages inappropriately include dispensing fees, which the government would have paid regardless of which antihypertension (or antidiabetic) drug was dispensed. Similarly, Prof. McFadden fails to offset damages with the costs of other drugs that would have been prescribed but-for the challenged conduct. Economic damages should account for costs the government would have incurred if Novartis's subject drugs had not been prescribed.

(150) As I explained in section IV.C, the government paid reimbursements that included both a payment for the cost of the drug (the "ingredient cost") and a dispensing fee. However, because a dispensing fee would have been paid regardless of which antihypertension (or antidiabetic) drug was prescribed, dispensing fees should be excluded from Prof. McFadden's damages calculations. Indeed, this

correction is conservative from Novartis's perspective because some programs paid higher dispensing fees for generic drugs.[218]

(151) I correct Prof. McFadden's damages calculations to exclude dispensing fees using one of three methodologies depending upon the program and source of information relied on by Prof. McFadden. First, for TRICARE expenditures and Medicaid expenditures where Prof. McFadden relies on claims data, I simply exclude the dispensing fee identified in the claims data for each challenged prescription. Second, for Medicaid expenditures where Prof. McFadden relies on IMS Health data, I reduce damages by an amount that corresponds to the average dispensing fee for that state and quarter. Finally, for Medicare Part D, because I have not been provided sufficient data to link the claims data with the government impact data relied on by Prof. McFadden, I reduce damages by an amount that corresponds to the average fraction represented by the dispensing fee in the Medicare Part D claims data.

(152) As shown in Figure 32 below, Prof. McFadden's failure to deduct dispensing fees significantly inflates his damages calculations. Specifically, excluding dispensing fees reduces damages by about 2%, from $513.6 million to $503.6 million. Similarly, excluding dispensing fees from a partially corrected version of Prof. McFadden's model reduces damages from $229.5 million to $224.9 million.

Figure 32: Summary of Prof. McFadden's damages (in millions) after removing dispensing fees

Adjustment to challenged claims	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Deduct dispensing fees	$503.6	$22.1	$224.9	$0.8

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

(153) In addition to dispensing fees, I also correct Prof. McFadden's damages calculations by offsetting damages with the costs the government would have incurred if a competing non-Novartis drug had been prescribed. Because the government has not made any allegation of medical non-necessity, patients would have received a prescription for a competing product had they not been prescribed one

[218] "[S]chedules often attempt to influence the pharmacist to dispense generics instead of brand-name equivalents by offering a premium for dispensing generics. This premium can be a higher dispensing fee, a higher price relative to the ingredient cost, or both." Frank Neuhauser, et al., "Commission on Health and Safety and Workers' Compensation Study of the Cost of Pharmaceuticals in Workers' Compensation," accessed Nov. 8, 2017,http://www.dir.ca.gov/chswc/pharmacy/pharmareport063000.html. In 2011, New York Medicaid paid dispensing fees of $4.50 and $3.50 for generics and brands, respectively. https://downloads.cms.gov/cmsgov/archived-downloads/MedicaidGenInfo/downloads/NY-11-61-Att.pdf.

of the subject drugs. Under this scenario, the government would still have been responsible for reimbursing for the competing product. Thus, I deduct the weighted average reimbursement of competing products in the same therapeutic class as the subject drug.[219]

(154) As shown in Figure 33 below, Prof. McFadden's failure to offset the costs of competing non-Novartis drugs significantly inflates his damages calculations. Specifically, offsetting with the costs the government would have incurred in a competing non-Novartis drug had been prescribed reduces damages by over 86%, from $513.6 million to $71.5 million. Similarly, offsetting these costs from a partially corrected version of Prof. McFadden's model reduces damages from $229.5.4 million to $31.2 million.

Figure 33: Summary of Prof. McFadden's damages (in millions) after offsetting costs of competing drugs

Adjustment to challenged claims	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Offsetting costs of competing drugs	$71.5	$2.8	$31.2	<$0.0

Source: CMS State Drug Utilization Data (SDUD); Concerto event data; FDA Orange Book; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

IX.C. Results of combined corrections to Prof. McFadden's damages calculations

(155) While I am not able to correct all of the flaws in Prof. McFadden's model, correcting those I can address reduces his damages substantially. As shown in Figure 34 correcting all of these flaws and calculating incremental damages, as is appropriate from the standpoint of economics, reduces Prof. McFadden's damages from $513.6 million to less than $50 thousand.

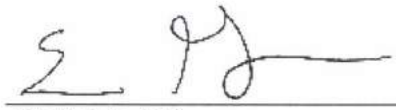
[219] For example, I identify the weighted average reimbursement of competing ARBs when offsetting Diovan (an ARB) damages. For classes where there are no competing products I identify the lowest cost antihypertension drug. Because I do not have exact information regarding the reimbursement of competing products for the various government programs at issue I use Medicaid State Drug Utilization Data (SDUD) to determine the weighted average reimbursement of competing products as a percentage of reimbursement for the subject drugs and reduce damages accordingly.

Figure 34: Summary of Prof. McFadden's damages (in millions) after correcting some flaws in his model and accounting for government rebates and dispensing fees

Adjustment to challenged claims/events[220]	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$513.6	$22.5	$229.5	$0.8
Remove managed Medicaid (MM) claims	$497.7	$21.7	$222.4	$0.7
Remove MM claims and additional lunch-and-learns (L&Ls) and correct meal spending	$432.1	$19.2	$195.5	$1.2
Remove MM claims, L&Ls, and pre-2010 Diovan, Exforge, and Tekturna (DET) events and correct meal spending	$154.7	$4.0	$69.6	$0.5
Remove MM claims, L&Ls, pre-2010 DET events, and pre-2010 DET+HCT events and prescriptions and correct meal spending	$97.0	$2.3	$40.4	$0.1
Remove MM claims, L&Ls, pre-2010 DET events, and pre-2010 DET+HCT events and prescriptions, rebates, and dispensing fees and correct meal spending	$81.2	$1.9	$33.7	<$0.1

Source: CMS State Drug Utilization Data (SDUD); Concerto event data; FDA Orange Book; IMS Health; McFadden Report; Novartis details data; Novartis samples data.

[220] There is no particular order to the adjustments shown. Should the Court deem it relevant, I can provide any combination of these adjustments.



Eric M. Gaier, PhD

December 11, 2017

Date

Appendix A. Curriculum vitae of Eric M. Gaier, PhD

Summary of experience

Dr. Eric M. Gaier is a founding member of Bates White, LLC. He has significant experience in the application of economic and statistical analysis to antitrust, civil fraud, and other economic and financial issues. Dr. Gaier specializes in analysis of class certification, pricing, and alleged anticompetitive conduct including market definition, market power, competitive impact, countervailing efficiencies, and damages.

Dr. Gaier has testified and consulted for government, law firm, and corporate clients across a variety of industries including health insurance, pharmaceuticals, medical devices, retail sales, agriculture, technology, commercial aviation, aerospace manufacturing, and defense procurement.

Areas of expertise

- Healthcare and life sciences
- Health insurance
- Pharmaceutical pricing and reimbursement
- Medical devices
- Class certification
- Damages analysis

Prior testimony within the past four years

- *Amgen Inc. v. Hospira, Inc.*, US District Court for the District of Delaware (Expert Declaration: May 2017).
- *Purdue Pharma L.P. v. Watson Laboratories, Inc.*, US District Court for the District of Delaware (Expert Reports: April 2016, June 2016; Deposition: June 2016)
- *State of Wisconsin v. Abbott Labs., Inc.*, Circuit Court of Dane County, Wisconsin (Expert Report: October 2015; Deposition: November 2015)
- *United States ex rel. Kevin N. Colquitt v. Abbott Labs., Inc.*, US District Court for the Northern District of Texas (Expert Report: July 2015; Deposition: August 2015)

- *Purdue Pharma L.P. v. Depomed, Inc.*, IPR before the Patent Trial and Appeal Board, United States Patent and Trademark Office (Declaration: December 2014; Deposition: January 2015)
- *In re WellPoint, Inc. Out-of-Network "UCR" Rates Litigation*, US District Court for the Central District of California (Expert Reports: March 2014, December 2015; Depositions: April 2014, February 2016)
- *State of Illinois v. Abbott Labs., Inc.*, Circuit Court of Cook County, Illinois (Expert Reports: January 2014, January 2015; Deposition: February 2014)
- *Center City Periodontists, P.C. v. Dentsply International, Inc.*, US District Court for the Eastern District of Pennsylvania (Expert Report: August 2013; Deposition: October 2013; Hearing: February 2016)

Professional experience

Prior to joining Bates White, Dr. Gaier served as an Associate of A.T. Kearney. Previously, he was a Research Fellow with the Technology Assessment Program of the Logistics Management Institute. Dr. Gaier has also served as a Consultant to the Panel on Statistical Methods for Evaluating Defense Systems of the National Research Council and as an Instructor in the Department of Economics at Duke University.

Education

- PhD, Economics, Duke University
- MA, Economics, Duke University
- BA, Economics, Florida State University

Publications

- "Forecasting and Economic Analysis for Aviation Systems Engineering," (with Peter F. Kostiuk), in *Air Transportation Systems Engineering*, Progress in Astronautics and Aeronautics Series, Volume 193, George L. Donohue, Andres G. Zellweger, Herman Rediess, and Christian Pusch, eds. Lexington, MA: American Institute of Aeronautics and Astronautics, 2001.
- "Strategic Information Generation and Transmission: The Evolution of Institutions in Department of Defense Operational Testing," (with Robert C. Marshall), in *Statistics Testing, and Defense*

Acquisition—Background Papers, Michael Cohen, Duane L. Steffey, and John E. Rolph, eds., Washington, DC: National Academy Press, 1999.

- "The Economic Impacts of Air Traffic Congestion," (with Peter F. Kostiuk and Dou Long), *Air Traffic Control Quarterly*, pp. 123–145, Volume 7, Number 2 1999.
- *The ASAC Air Carrier Cost-Benefit Model* (with Tara E. Santmire, Alexander P. Edlich, and Earl R. Wingrove), NASA Contractor Report 1999–208983, January 1999.
- *A Method for Forecasting the Commercial Air Traffic Schedule in the Future* (with Dou Long, David A. Lee, Jesse P. Johnson, and Peter F. Kostiuk), NASA Contractor Report 1999–208987, January 1999.
- *Modeling Air Traffic Management Technologies with a Queuing Network Model of the National Airspace System* (with Dou Long, David A. Lee, Jesse Johnson, and Peter F. Kostiuk), NASA Contractor Report 1999–208988, January 1999.
- *The ASAC Air Carrier Investment Model: Third Generation* (with Earl R. Wingrove, Jesse P. Johnson, and Tara E. Santmire), NASA Contractor Report 1998–207656, April 1998.
- *Air Cargo Operations Cost Database* (with Jesse P. Johnson), NASA Contractor Report 1998–207655, April 1998.

Professional associations

- American Economic Association
- American Bar Association (Associate Member)
- International Health Economics Association

Appendix B. Materials considered

B.1. Litigation documents

B.1.a. Depositions

- Deposition of Maribeth Dipinto-Moss, September 23, 2016.

B.1.b. Discovery documents

- NPCLSV_LIT000060636–0691
- NPCLSV_LIT000633432–3473
- NPCLSV_LIT001213363–3390
- NPCLSV_LIT001517018–7053
- NPCLSV_LIT001643057–3074
- NPCLSV00015272–5361

B.1.c. Expert reports

- Expert Report of Richard E. Goldberg, PhD., August 14, 2017.
- Expert Report of Professor Daniel McFadden on Behalf of Plaintiffs, August 14, 2017.
- Supplemental Expert Report of Professor Daniel McFadden on Behalf of Plaintiffs, September 22, 2017.
- Expert Report of Graham T. McMahon, M.D. M,M,Sc, August 14, 2017.
- Expert Report of Stanley J. Schneller, M.D. August 3, 2017.

B.1.d. Filings

- Amended Complaint in Intervention of the United States of America, August 26, 2013.

B.2. Data

- Access rebate data (NPCLSV_LIT12602041–2089, NPCLSV_LIT12602183–2214)
- Concerto event data (NPCLSV_LIT012419766–9773)
- EDGE Checkwriter data (NPCLSV_LIT012419774–9780)
- IMS Health data
- IMS Physician Master file (NPCLSV_LIT002169633)
- Medicaid rebates (NPCLSV_LIT12602039–2040)
- Medicaid State Drug Utilization data (SDUD)
- National Ambulatory Medical Care Survey (NAMCS) data
- Novartis details data (NPCLSV_LIT12602090–2182)
- Novartis samples data (NPCLSV_LIT12600810–2038)
- Orange Book data
- Pubmed data

B.3. Publicly available documents

B.3.a. Academic literature

- A. Colin Cameron and Pravin K. Trivedi, Regression Analysis of Count Data, 2nd edition, Cambridge University Press, 2013.
- A.H. Studenmund, B.K. Johnson, "Using Econometrics: A Practical Guide." Pearson (2016).
- Andrew T. Ching, Masakazu Ishihara, "Measuring the Informative and Persuasive Roles of Detailing on Prescribing Decisions," Management Science, 2012, 58 (7): pp. 1374—1387.
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B.3.b. Legislation

- 38 U.S.C. § 8126
- Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals, Fed. Reg. Vol 75, No. 199 (Oct. 15, 2010), https://www.federalregister.gov/documents/2010/10/15/2010-25712/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-inclusion-of-tricare.
- Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6003, 120 Stat. 60–61 (2006).
- Determination of AMP, 42 C.F.R. § 447.504 (2010).
- National Defense Authorization Act for Fiscal Year 2008, H.R. 1585, 110th Cong. (Dec. 2007). *Available at* https://www.gpo.gov/fdsys/pkg/CRPT-110hrpt477/pdf/CRPT-110hrpt477.pdf.
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B.3.c. Websites, news articles, and other sources

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Appendix C. Prof. McFadden's assertion that Novartis improperly maintained its share of antihypertension prescriptions is erroneous

(156) In his "Background" section, Prof. McFadden asserts that Novartis maintained what he considers to be an unexpectedly high share of antihypertension drugs, at least through 2011, in the face of increasing competition from generic manufacturers.[221] Prof McFadden asserts that Novartis was able to maintain its share, in part, through marketing programs. Specifically, Prof. McFadden asserts:

> The data reflects that Novartis, unlike its brand name competitors, made a successful effort to maintain its market share in the face of this competition. According to Novartis's 2002 20-F report to the Security and Exchange Commission, the company responded to the competition from generics using several strategies including "marketing efforts to increase brand awareness and loyalty toward our products.[222]

(157) However, Prof. McFadden's assertions fail to appreciate how generic competition impacts brand-name drugs and do not establish any connection between Novartis's challenged conduct and prescriptions for Novartis's subject drugs. In the first instance, I note that Prof. McFadden's own model identifies only 381,000 incremental government-reimbursed prescriptions purportedly caused by the alleged kickbacks. To put this in context, 381,000 prescriptions represent less than 0.01% of the total subject drugs prescribed during the relevant time period. Thus, based upon Prof. McFadden's own model, there is no credible connection between Novartis's challenged conduct and any assertion that Novartis improperly maintained its share of antihypertension drugs.

(158) More fundamentally, Prof. McFadden's assertions fail to appreciate that most of the impact of generic entry on market share is focused on the equivalent brand-name drug.[223] That is, generic drugs compete most directly with their equivalent brand-name (and generic) molecule and spillover effects to other brand-name drugs are typically small. Prof. McFadden acknowledges that only two of Novartis's subject drugs faced generic entry prior to 2011, but he fails to appreciate that this fact explains Novartis's share of antihypertension drugs.[224]

(159) Figure 35 below demonstrates the impact of generic entry for each of Novartis's subject drug that faced a generic equivalent. Specifically, as shown in Figure 35, prescriptions for each of Novartis's

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[221] McFadden Report, ¶¶ 17–19, Figure 1, Figure 2.

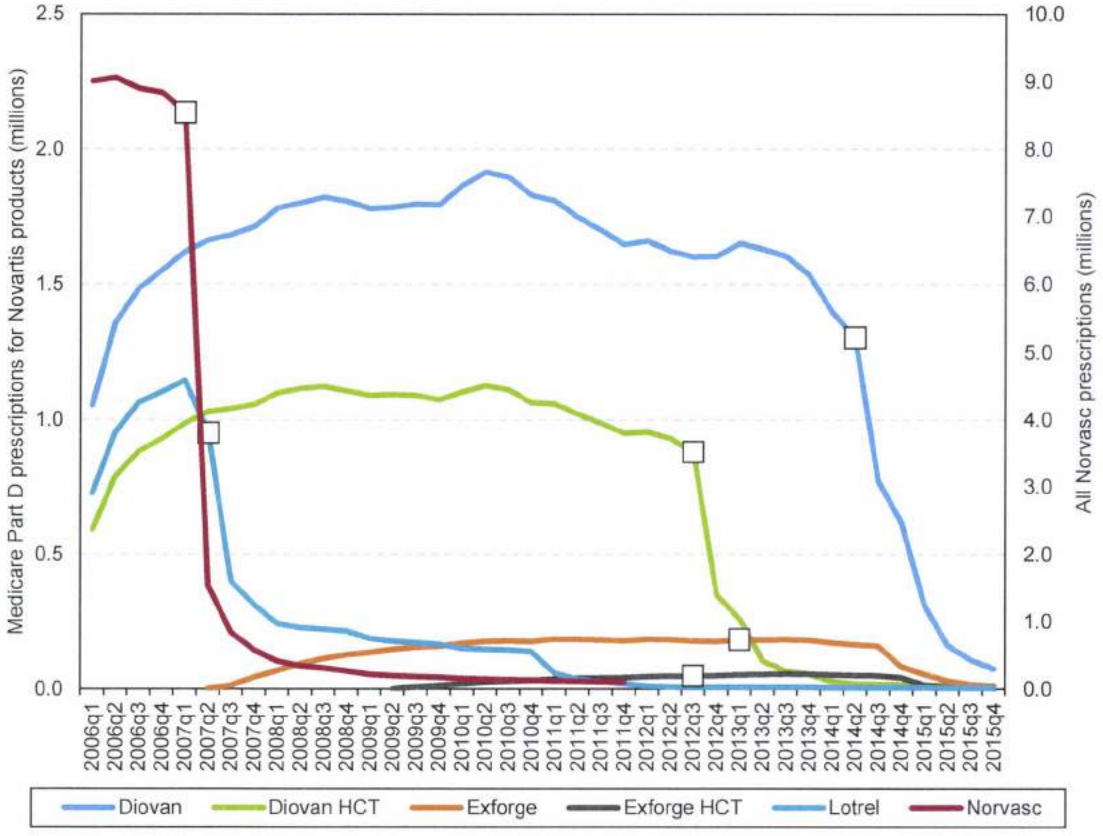
[222] McFadden Report, ¶ 17.

[223] This is because the pharmacist can generally substitute a brand-name drug for its generic equivalent without consulting the prescribing doctor. However, the pharmacist cannot substitute a generic drug for the brand-name version of a different drug without permission from the prescribing doctor.

[224] McFadden Report, ¶ 17.

subject drugs fall precipitously upon entry of a generic equivalent. For example, prescriptions for both Diovan and Diovan HCT fall by approximately 90% within a year of facing a generic equivalent. Prescriptions for Lotrel fell by over 75% within a year as well. As also shown in Figure 35, these steep declines are consistent with the reduction in prescriptions that Norvasc, a blockbuster calcium channel blocker manufactured by Pfizer, encountered when it faced generic competition earlier in the relevant period.

Figure 35: Medicare prescriptions for subject drugs that faced entry of a generic equivalent



Source: IMS Health; Medicare claims; Food and Drug Administration. "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations." Accessed between March 2016 and August 2017, https://www.accessdata.fda.gov/scripts/cder/ob/

Note: Squares denote approval of generic equivalent.

Appendix D. Prof. McFadden ignores an obvious selection bias in comparing prescribing patterns of doctors who allegedly received kickbacks with those who did not

(160) Prof. McFadden provides figures (and a table) purporting to illustrate the average number of prescriptions per month written by three different groups of doctors: (1) doctors who did not participate in Novartis's events, (2) doctors who participated in Novartis's events, but did not receive alleged kickbacks, and (3) doctors who received at least one alleged kickback.[225] Based upon these figures, Prof. McFadden concludes:

> The figures demonstrate that – across these various scenarios – doctors who met the kickback criteria consistently prescribed more of the subject drugs on average than doctors who did not.[226]

(161) However, Prof. McFadden's figures are the result of a simple selection bias and do not establish any connection between Novartis's challenged conduct and prescriptions for Novartis's subject drugs. As is common in the pharmaceutical industry, Novartis segmented doctors into volume-based prescribing tiers and targeted its marketing efforts to the highest-volume prescribers.[227] Hence, high-volume prescribers received more overall promotion including detailing, sampling, and events. Consequently, high-volume prescribers are more likely to have attended events and, hence, are more likely to be identified by Dr. Goldberg as having received an alleged kickback. Importantly, Novartis's prescribing tiers were based upon the total prescriptions written by the doctor within the relevant drug class (e.g., antihypertension drugs), not just prescriptions for Novartis's drugs.[228] Thus, doctors who prescribed high volumes of Novartis's drugs also tended to prescribe high volumes of drugs marketed by other manufacturers.

(162) In Figure 36 below, I illustrate the selection bias underlying Prof. McFadden's observations by adding a measure of detailing to his Figure 4 (concerning Diovan HCT). Specifically, on a second axis, I graph the average number of detailing visits received by the three groups of doctors identified by Prof. McFadden for Diovan HCT. As shown in Figure 36, I observe the same pattern for detailing visits that Prof. McFadden observed for prescriptions. That is, doctors who met the "kickback

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[225] McFadden Report, ¶¶ 34–36, Table 5, Figures 4–6, Appendix D.1 Figures 1–20.

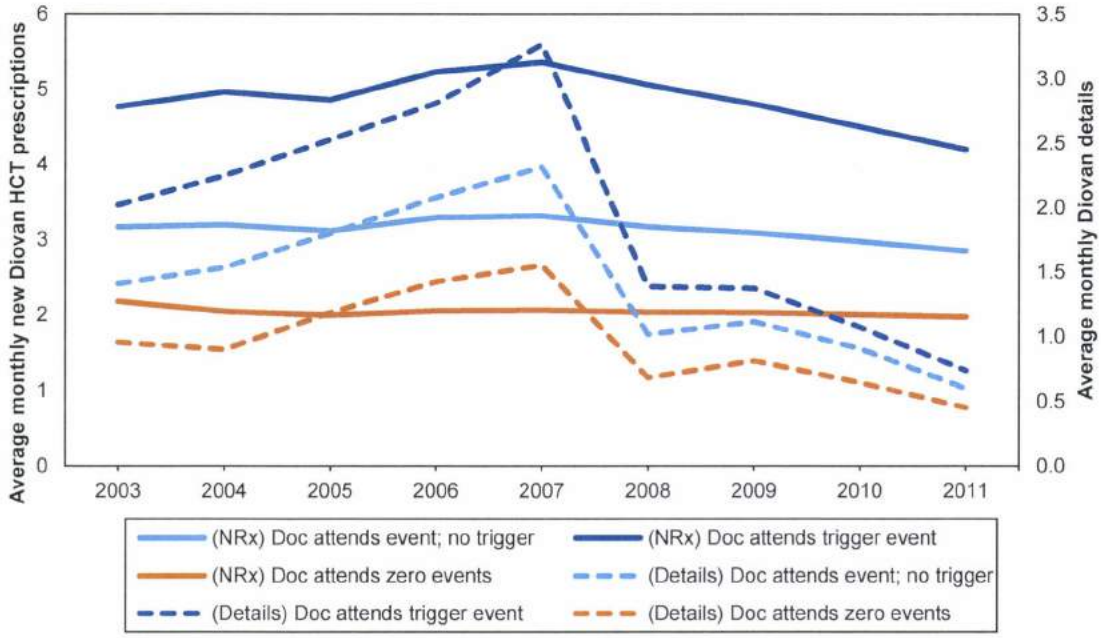
[226] McFadden Report, ¶ 36.

[227] Deposition of Maribeth Dipinto-Moss, September 23, 2016 [hereinafter Dipinto-Moss Dep.] at 57:10–22 "Q. What about above that on the previous page, do you see where it says tier and the numbers and Lotrel and Diovan? A. Yes. Q. What is that? A. The doctors were tiered based on and ranked, the tiers one through five were based on their, I guess, volume of -- of any hypersensitive agents and what their potential could be. So a tier one would be a very important physician, and you usually had to call on them more and see them more than a tier five."

[228] Dipinto-Moss Dep. at 57:15–19 "A. The doctors were tiered based on and ranked, the tiers one through five were based on their, I guess, volume of -- of any hypersensitive agents and what their potential could be."

criteria" also received significantly more detailing visits than doctors who did not. Similar results are shown for other subject drugs in Appendix D.1.

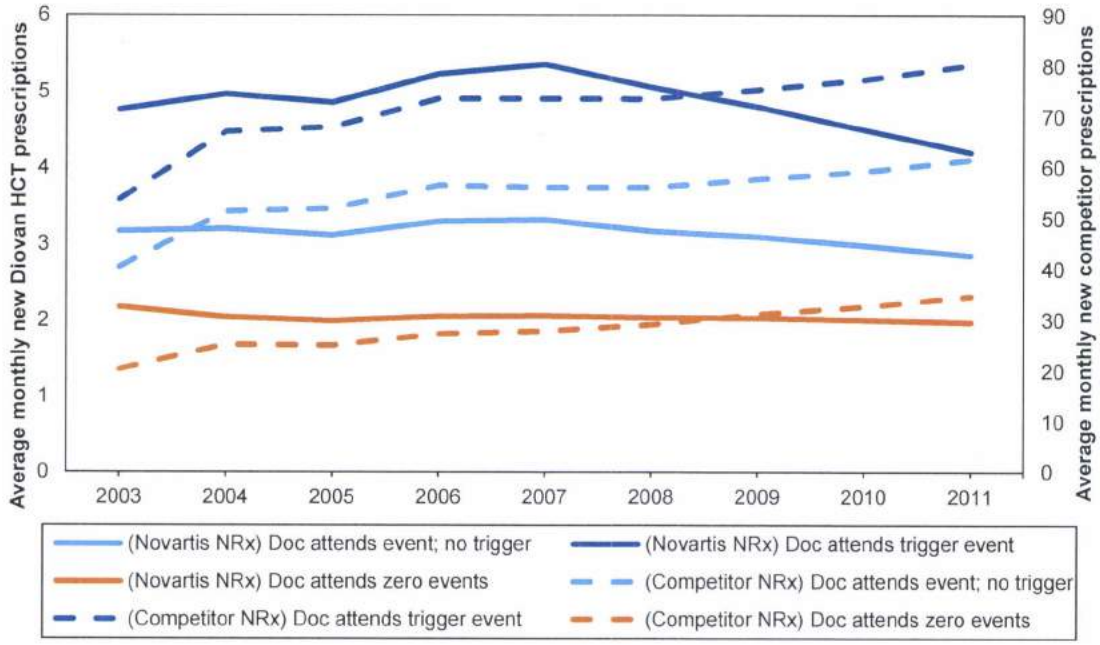
Figure 36: Diovan HCT prescribing and detailing, by Prof. McFadden's provider segments



Source: IMS Health; Novartis details data.

(163) In Figure 37 below, I also illustrate the selection bias underlying Prof. McFadden's observations by adding a measure of prescriptions for competing non-Novartis antihypertension drugs to his Figure 4 (concerning Diovan HCT). Specifically, on a second axis, I graph the average number of new competitor prescriptions written by the three groups of doctors identified by Prof. McFadden for Diovan HCT. As shown in Figure 37, I observe the same pattern for competing prescriptions that Prof. McFadden observed for Diovan HCT prescriptions. That is, doctors who met the "kickback criteria" also prescribed significantly more competing antihypertension drugs than doctors who did not. Similar results are shown for other subject drugs later in Appendix D.2.

Figure 37: Prescribing of Diovan HCT and non-Novartis antihypertension drugs, by Prof. McFadden's provider segments

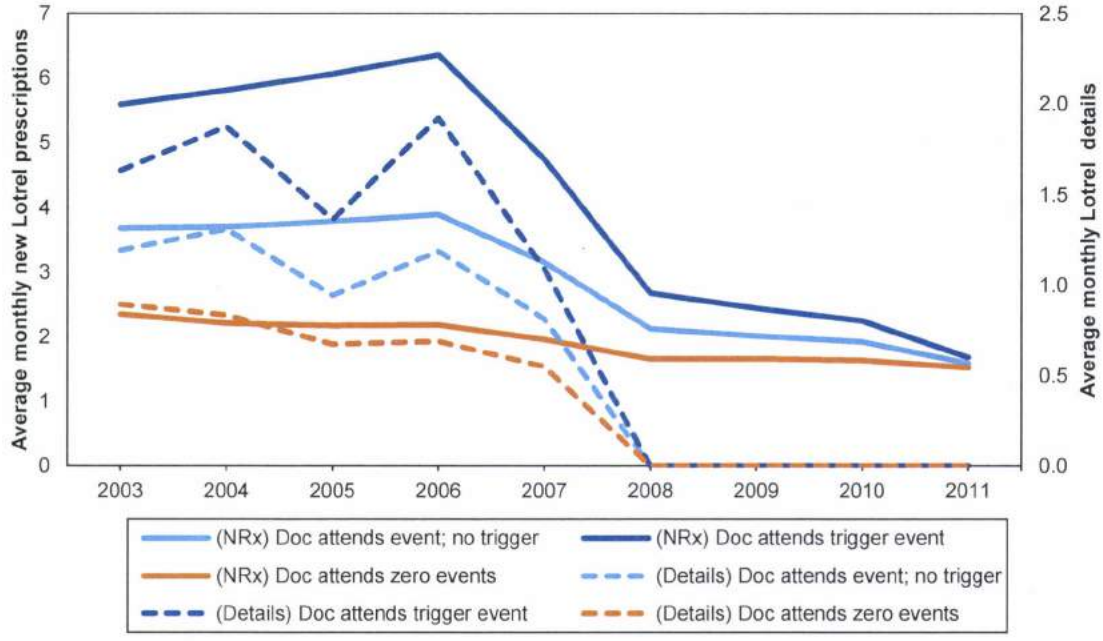


Source: IMS Health.

(164) These results demonstrate that Prof. McFadden's observations are explained by a simple selection bias and do not establish any connection between Novartis's challenged conduct and prescriptions for Novartis's subject drugs.

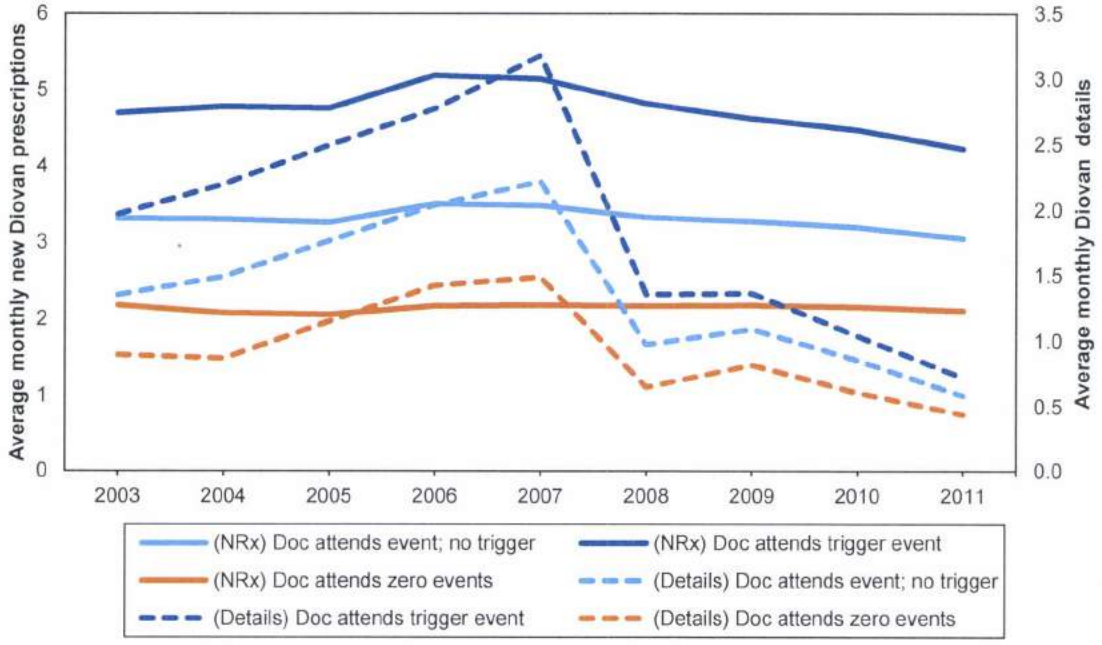
D.1. Additional Novartis prescribing and detailing by Prof. McFadden's provider segments

Figure 38: Lotrel prescribing and detailing, by Prof. McFadden's provider segments



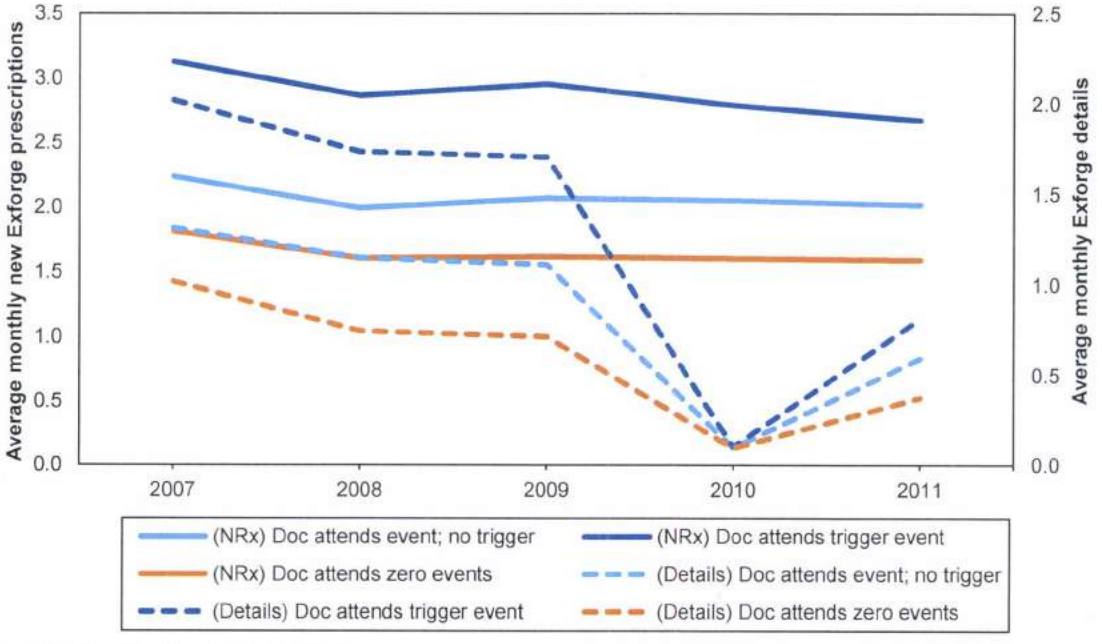
Source: IMS Health; Novartis details data.

Figure 39: Diovan prescribing and detailing, by Prof. McFadden's provider segments



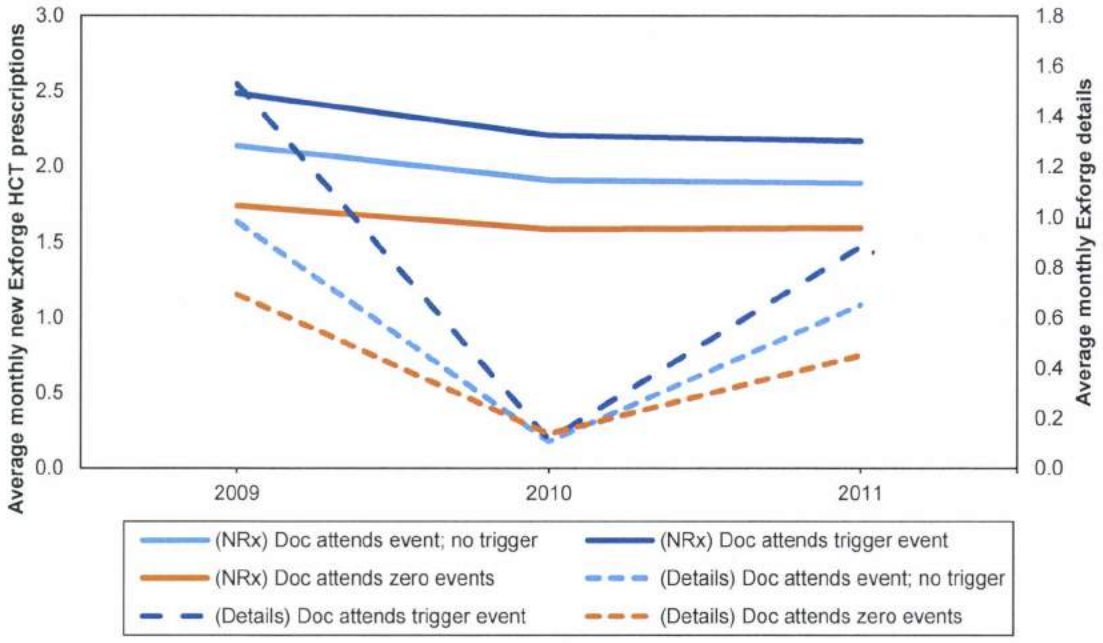
Source: IMS Health; Novartis details data.

Figure 40: Exforge prescribing and detailing, by Prof. McFadden's provider segments



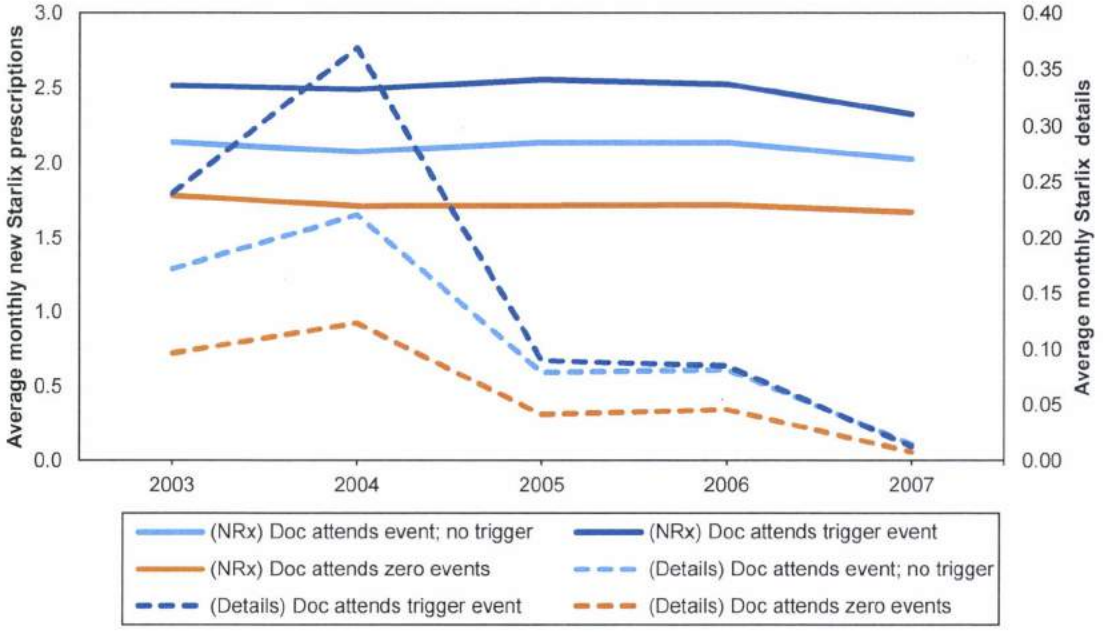
Source: IMS Health; Novartis details data.

Figure 41: Exforge HCT prescribing and detailing, by Prof. McFadden's provider segments



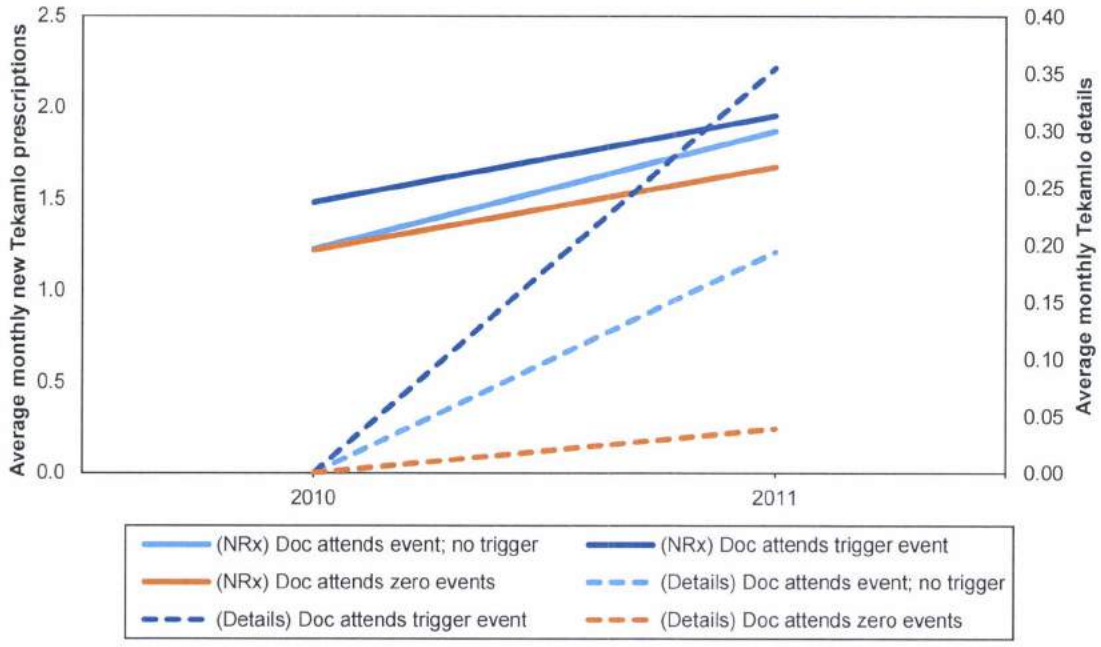
Source: IMS Health; Novartis details data.

Figure 42: Starlix prescribing and detailing, by Prof. McFadden's provider segments



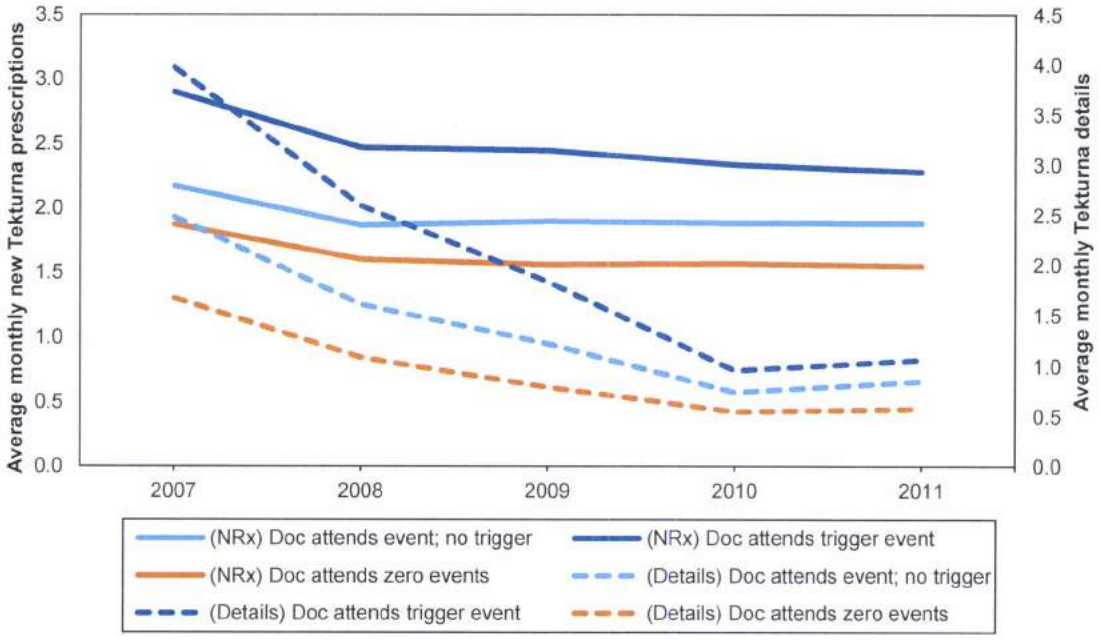
Source: IMS Health; Novartis details data.

Figure 43: Tekamlo prescribing and detailing, by Prof. McFadden's provider segments



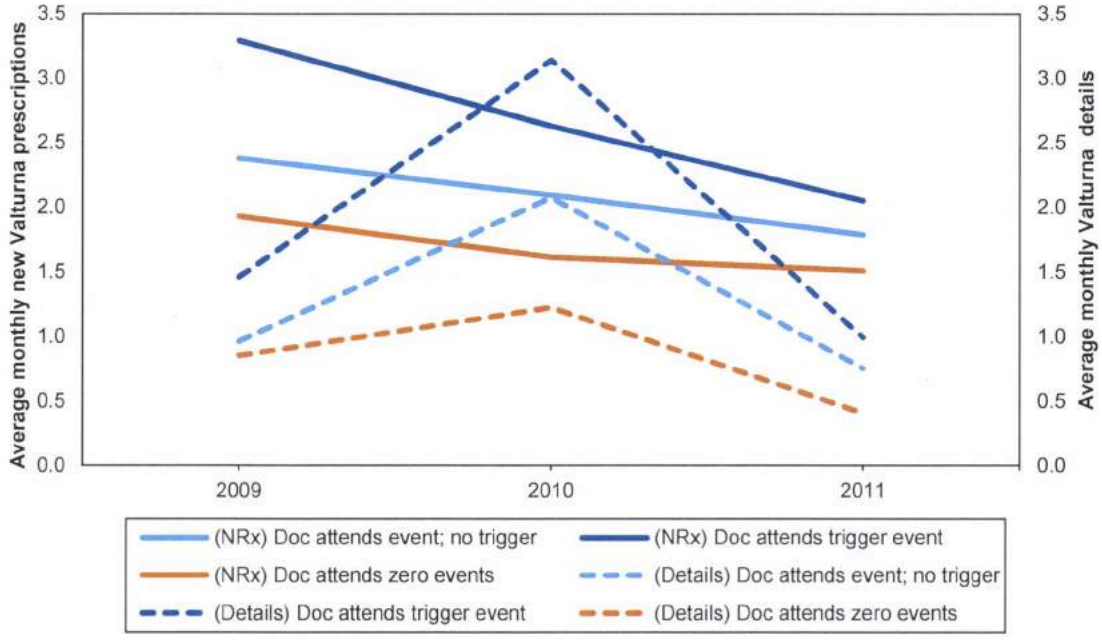
Source: IMS Health; Novartis details data.

Figure 44: Tekturna prescribing and detailing, by Prof. McFadden's provider segments



Source: IMS Health; Novartis details data.

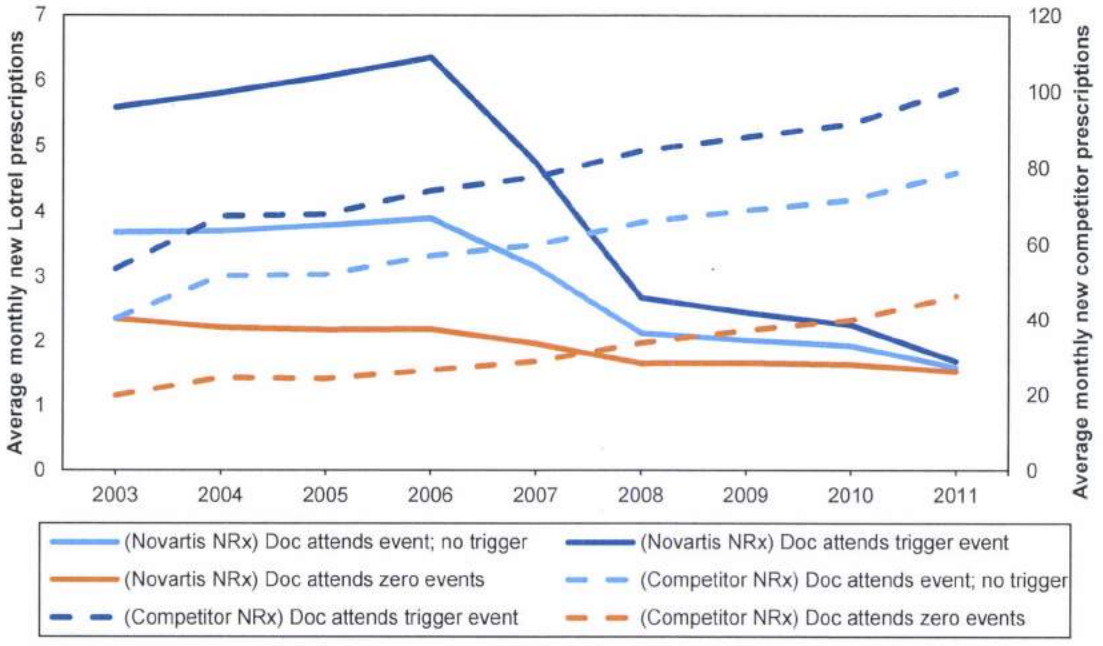
Figure 45: Valturna prescribing and detailing, by Prof. McFadden's provider segments



Source: IMS Health; Novartis details data.

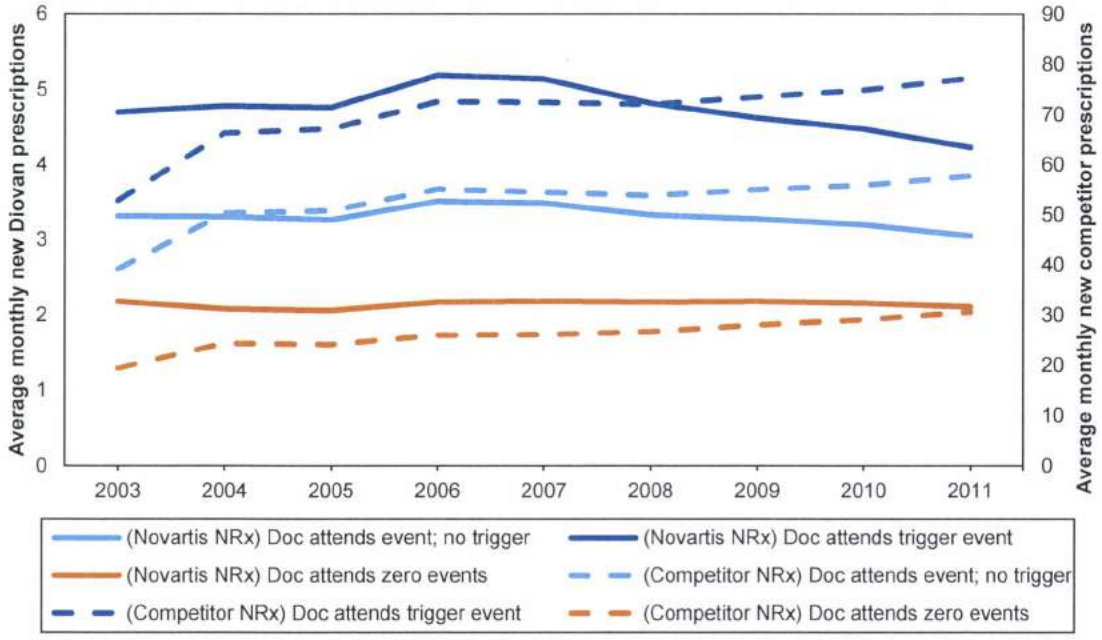
D.2. Additional Novartis and competitor prescribing by Prof. McFadden's provider segments

Figure 46: Prescribing of Lotrel and non-Novartis antihypertension drugs, by Prof. McFadden's provider segments



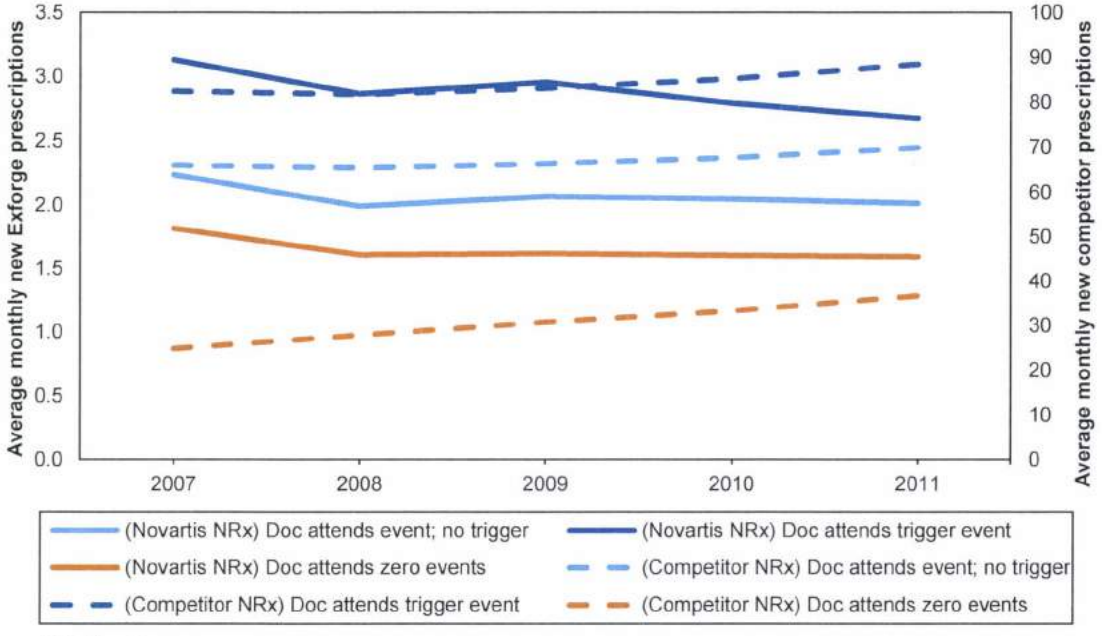
Source: IMS Health.

Figure 47: Prescribing of Diovan and non-Novartis antihypertension drugs, by Prof. McFadden's provider segments



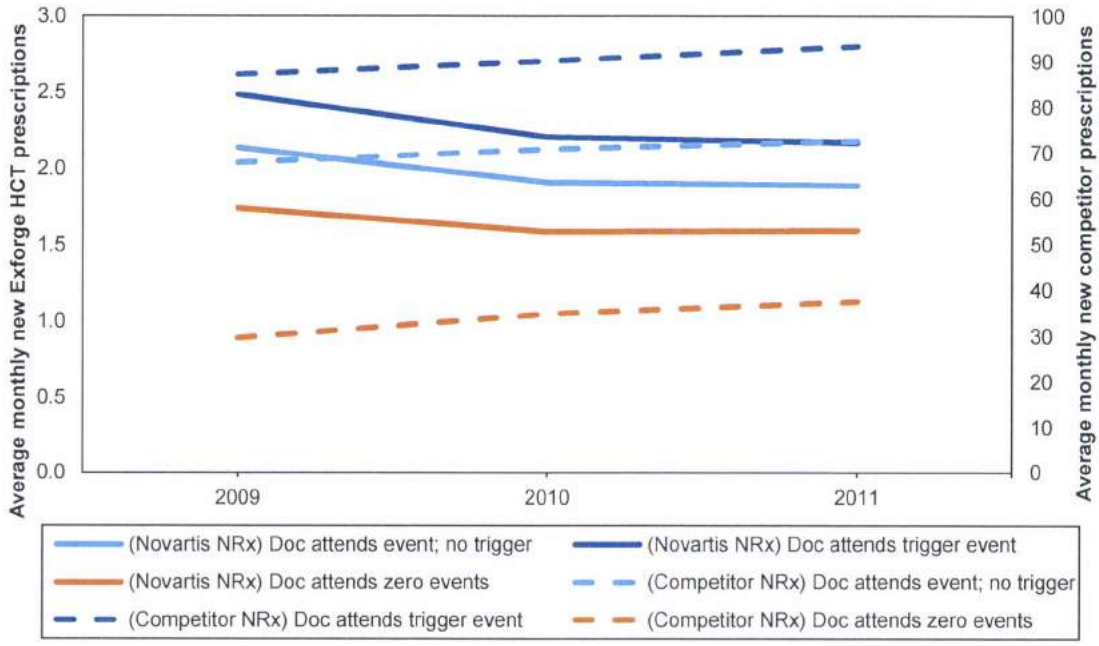
Source: IMS Health.

Figure 48: Prescribing of Exforge and non-Novartis antihypertension drugs, by Prof. McFadden's provider segments



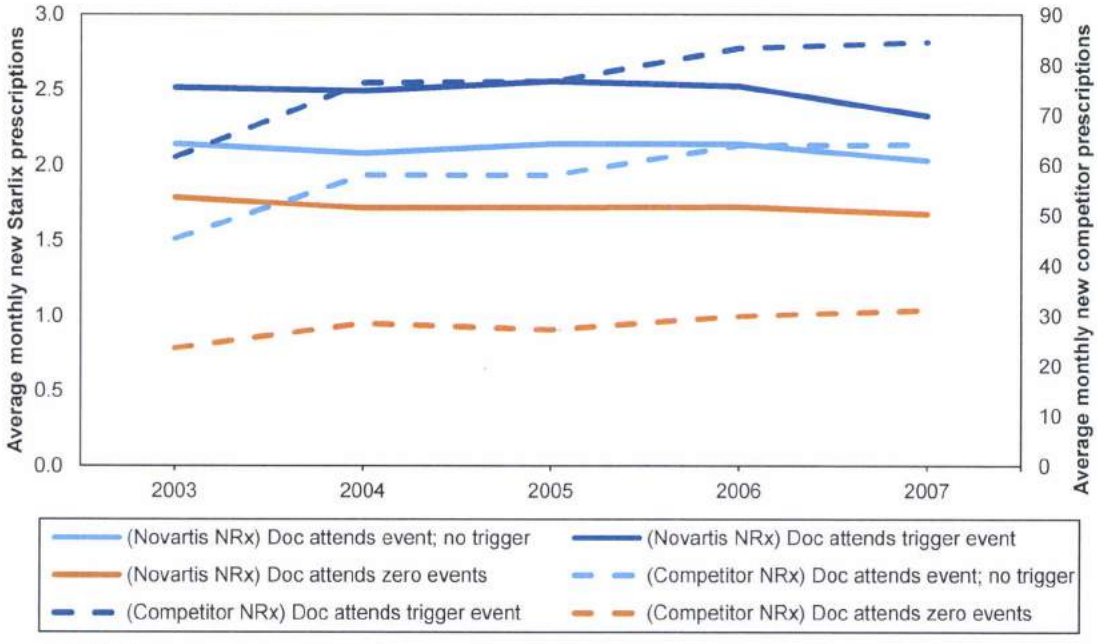
Source: IMS Health.

Figure 49: Prescribing of Exforge HCT and non-Novartis antihypertension drugs, by Prof. McFadden's provider segments



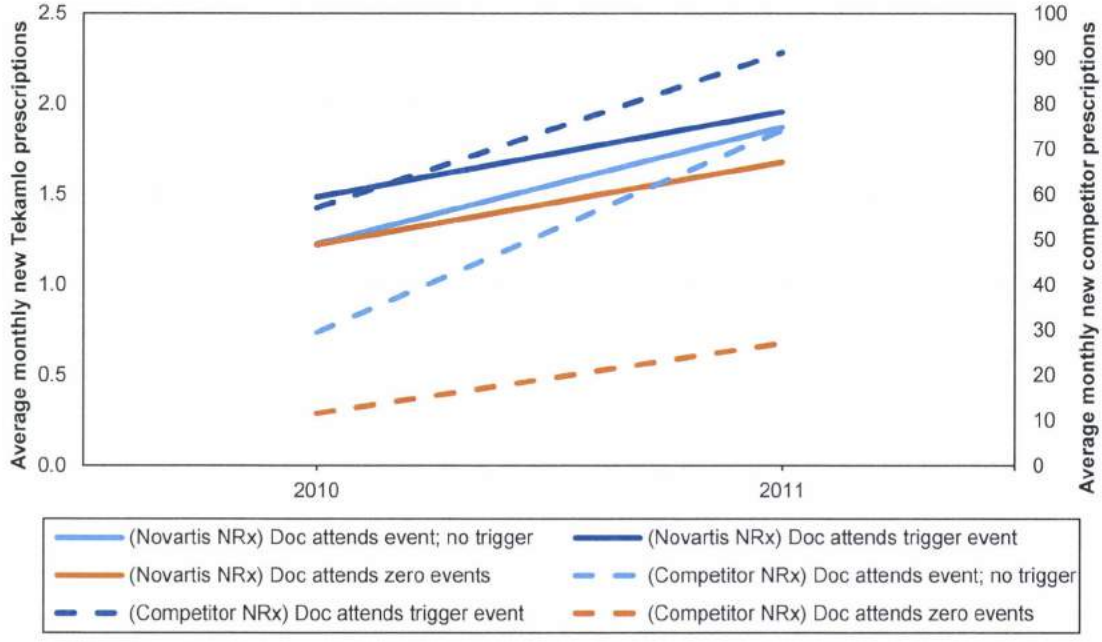
Source: IMS Health.

Figure 50: Prescribing of Starlix and non-Novartis antihypertension drugs, by Prof. McFadden's provider segments



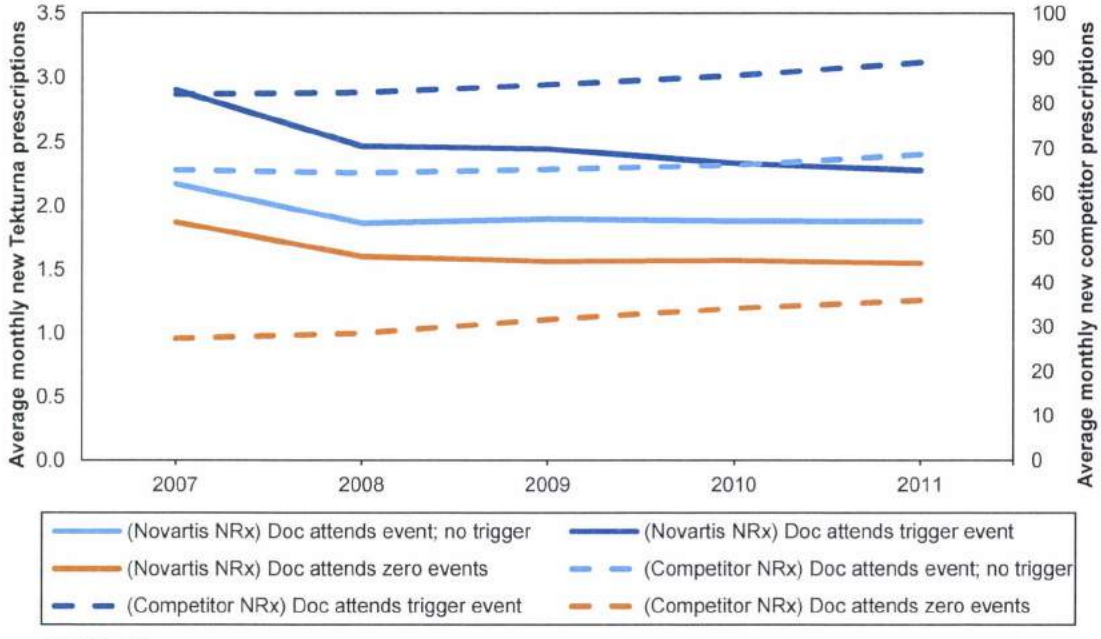
Source: IMS Health.

Figure 51: Prescribing of Tekamlo and non-Novartis antihypertension drugs, by Prof. McFadden's provider segments



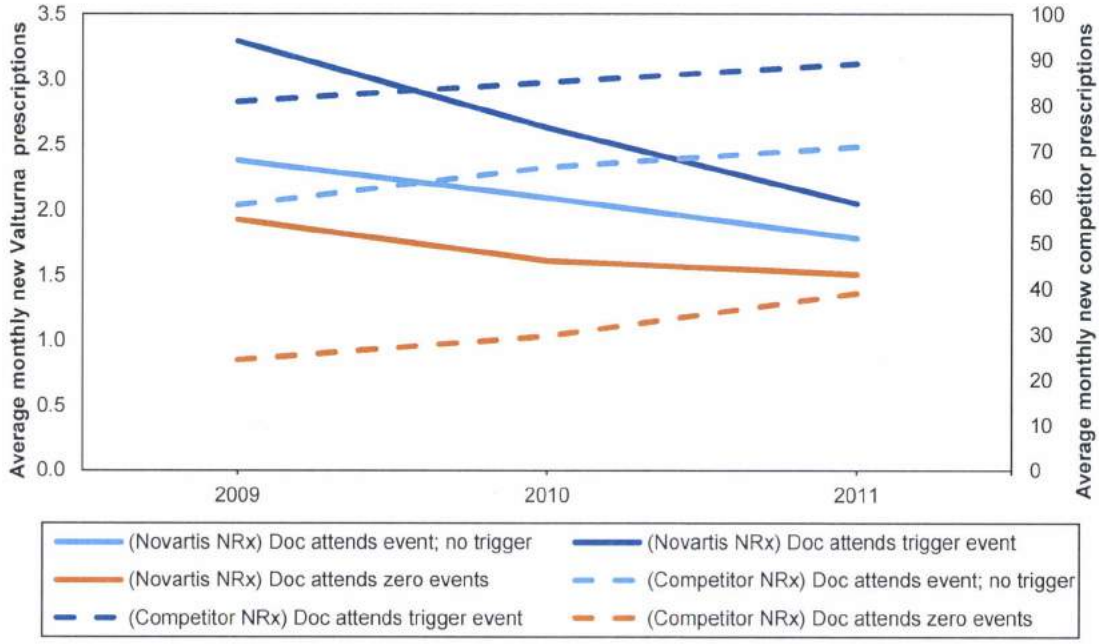
Source: IMS Health.

Figure 52: Prescribing of Tekturna and non-Novartis antihypertension drugs, by Prof. McFadden's provider segments



Source: IMS Health.

Figure 53: Prescribing of Valturna and non-Novartis antihypertension drugs, by Prof. McFadden's provider segments



Source: IMS Health.

Appendix E. Impact of corrections to Prof. McFadden's original damage calculations

Figure 54: Prof. McFadden's original damages (in millions) after corrections to his analyses

Scenario	Prof. McFadden's model		Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact	
	All claims	Incremental claims	All claims	Incremental claims
Baseline	$436.5	$18.7	$195.7	$0.5
Correcting for errors in input data[229]	$84.9	$2.0	$35.5	$0.1
Correcting for errors in input data and calculating economic damages[230]	$74.2	$1.7	$30.9	<$0.1

Source: Concerto event data; Government claims data; IMS Health; McFadden Report; McFadden supplemental materials; Novartis details data; Novartis samples data.

[229] This consists of removing the additional lunch-and-learn events Dr. Goldberg fails to exclude, correcting Dr. Goldberg's double counting of meal spend at some multiproduct events, removing events for DET events prior to 2010, and removing events and claims for DET HCT events prior to 2010.

[230] In addition to the corrections to the input data, this consists of deducting rebates, deducting dispensing fees, and excluding managed Medicaid claims

Appendix F. Lunch-and-learn identification

I identify an event as a lunch-and-learn if all of the following criteria are met:

- The *event_type* field is a "REF-ROUNDTABLE;"
- Any of the lunch-and-learn terms below are in the respective Concerto data fields; and
- None of the non-lunch-and-learn terms below are in the respective Concerto data fields.

F.1. Lunch-and-learn terms

- From *evt_titl* field:
  - "LUNCH"
- From *location* field:
  - " DELI"
  - "7-ELEVEN"
  - "ADULT"
  - "ASSOC"
  - "BAGEL"
  - "BAKERY"
  - "BOSTON MARKET"
  - "BREAD"
  - "BREAKFAST"
  - "CARDIO"
  - "CARE"
  - "CENTER"
  - "CHICK-FIL-A"
  - "CHIPOTLE"
  - "CLINIC"
  - "COFFEE"

- "COMMUNITY"
- "DELI "
- "DELIVERY"
- "DEPARTMENT"
- "DEPT"
- "DIAGNOSTIC"
- "DOCTOR"
- "DR "
- "DR."
- "DRS "
- "DRS."
- "DUNKIN"
- "ENDO"
- "FAMILY"
- "GIANT"
- "GROCERY"
- "GROUP"
- "GRP"
- "HEALTH"
- "HIP CENTER"
- "HIP CENTR"
- "HIP CTR"
- "HOSP"
- "INTERNAL"
- "INTERNISTS"
- "KROGER"
- "LUNCH"
- "MEDICAL"

- "MEDICINE"
- "NEPHROLOGY"
- "OFFICE"
- "PANARA"
- "PANERA"
- "PAPA JOHN"
- "PHYS"
- "POTBELLY"
- "PRACTICE"
- "PRIMARY"
- "QUIZNO"
- "SMOOTHIE"
- "SNACK"
- "SPECIALIST"
- "STARBUCK"
- "SUBWAY"
- "WEGMANS"

- From *location_type* field:
  - "OFFICE"

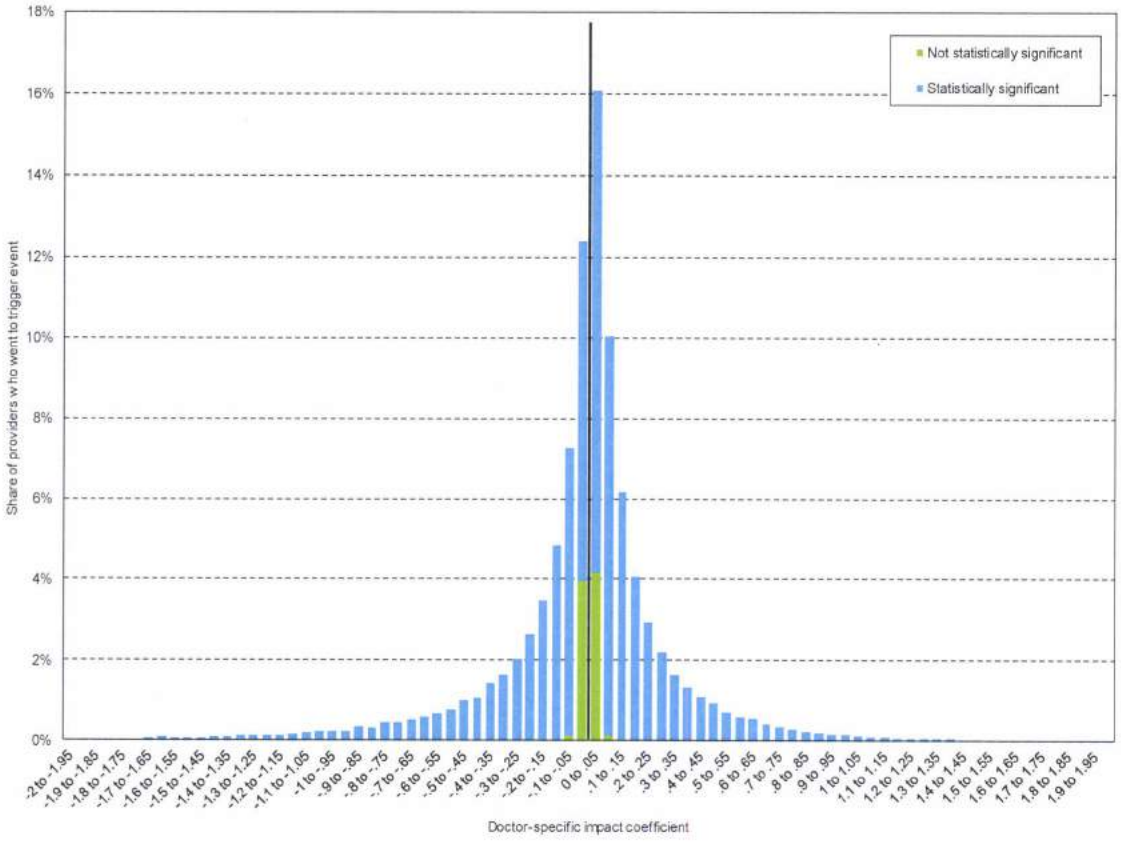
F.2. Non-lunch-and-learn terms

- From *evt_titl* field:
  - "DINNER"
- From *location* field:
  - "DINNER"
  - "HOSPITALITY"
  - "HOTEL"
  - "NOBU"

- "REST"
- "RSTR"

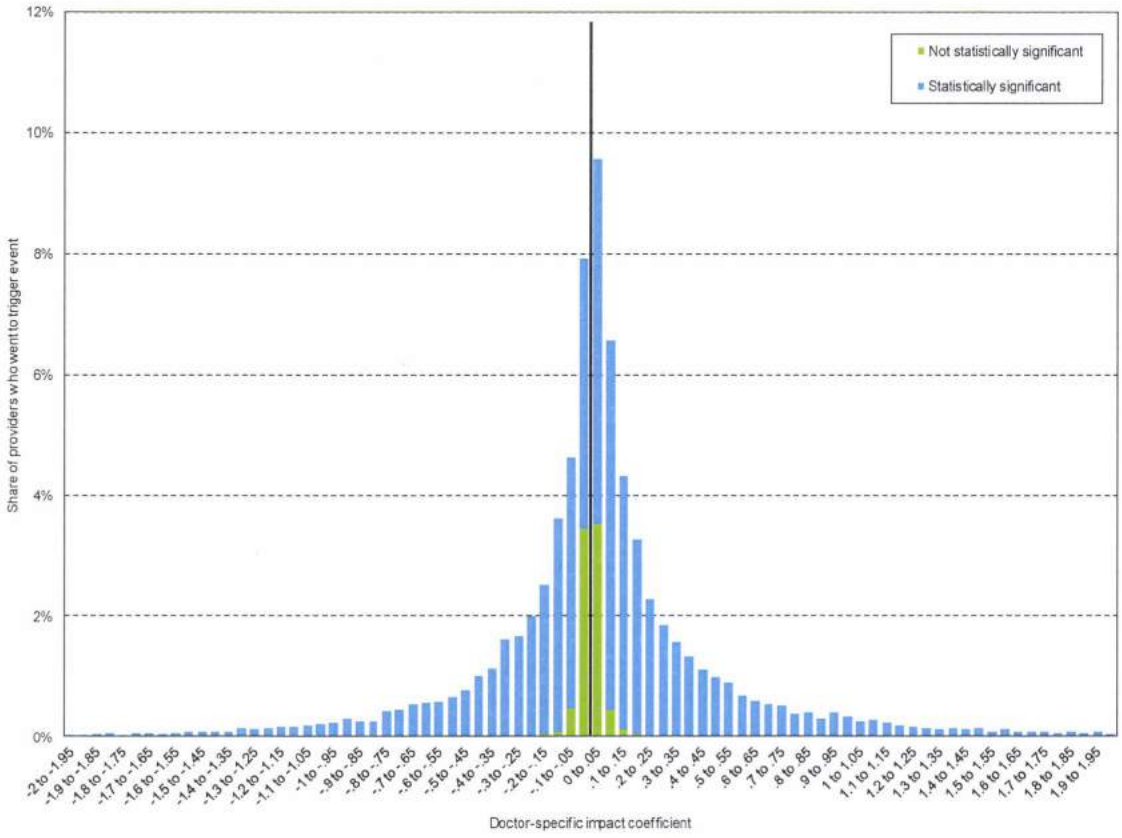
Appendix G. Doctor-specific impact coefficients

Figure 55: Distribution of doctor-specific impact coefficients for Diovan with statistical significance



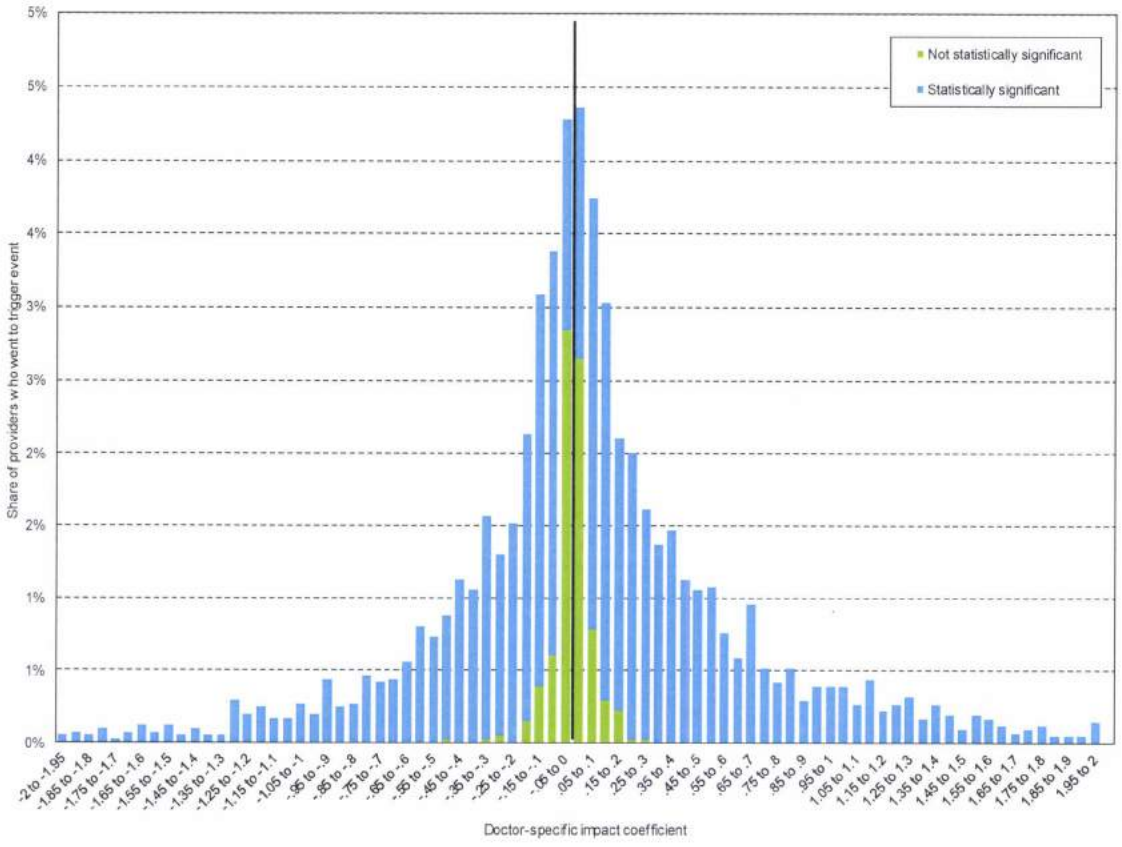
Source: Concerto event data; IMS Health.

Figure 56: Distribution of doctor-specific impact coefficients for Exforge with statistical significance



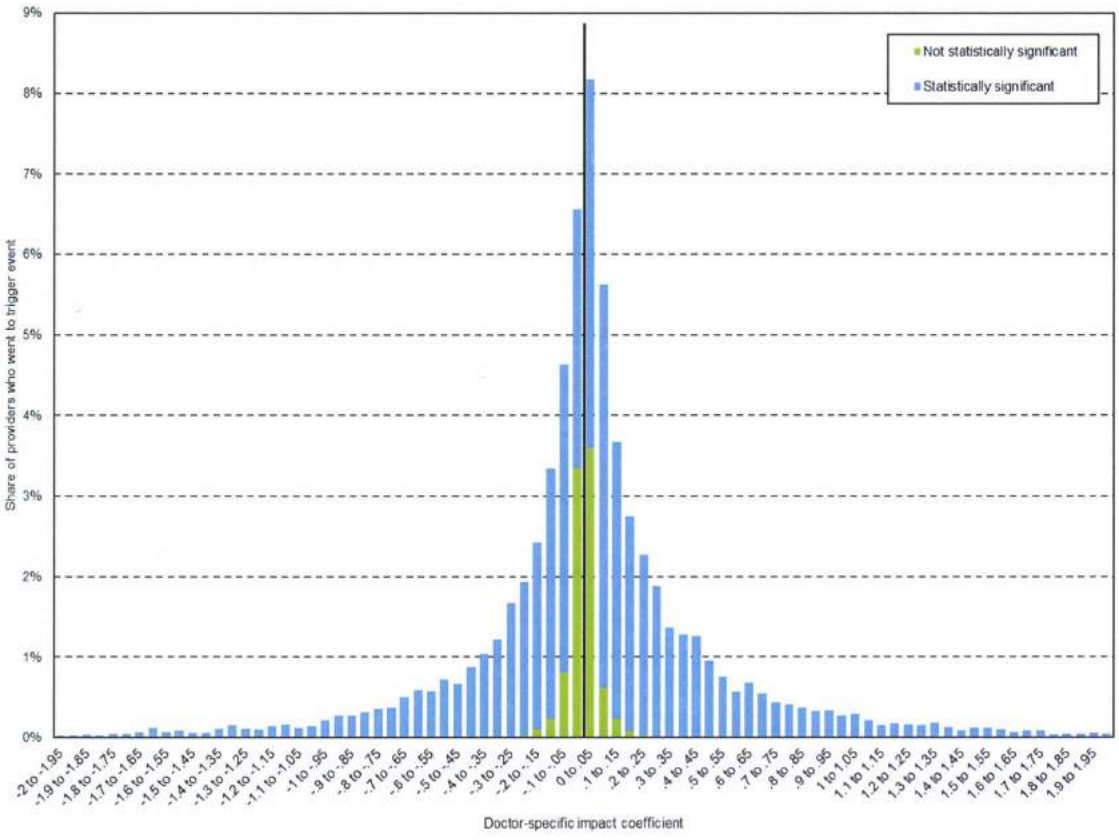
Source: Concerto event data; IMS Health.

Figure 57: Distribution of doctor-specific impact coefficients for Exforge HCT with statistical significance



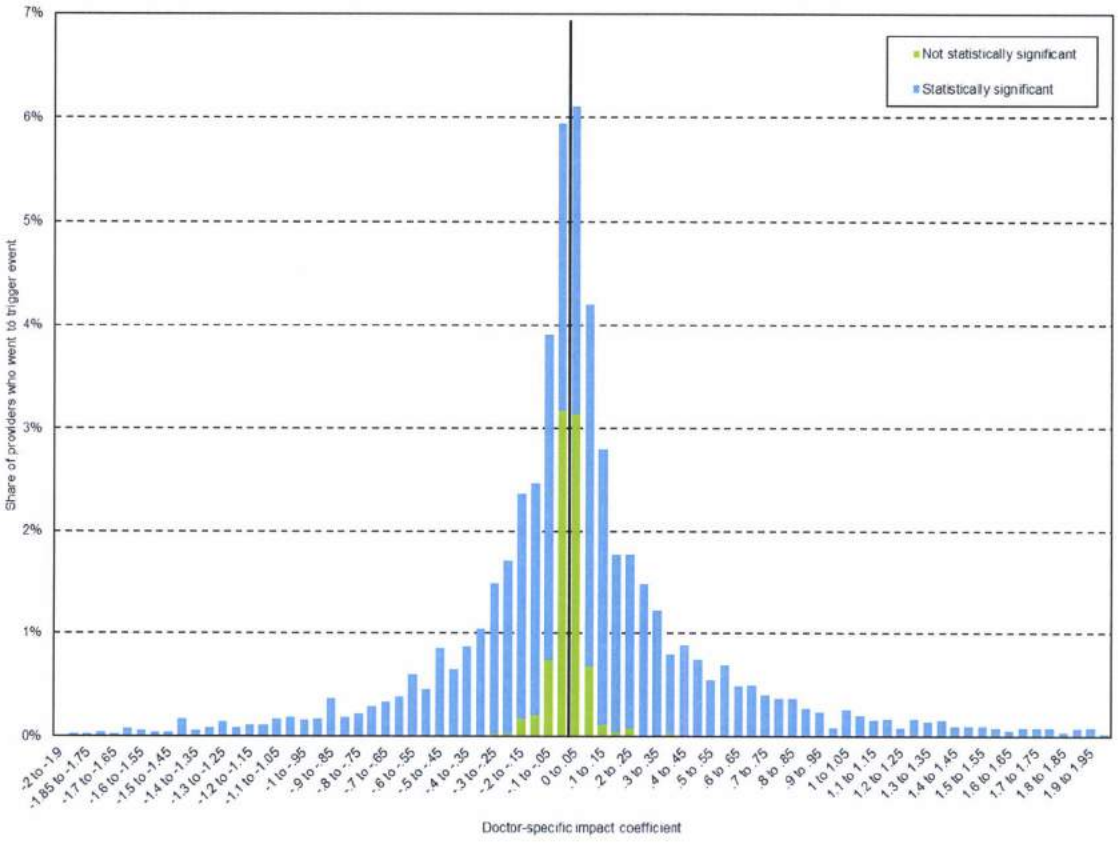
Source: Concerto event data; IMS Health.

Figure 58: Distribution of doctor-specific impact coefficients for Tekturna with statistical significance



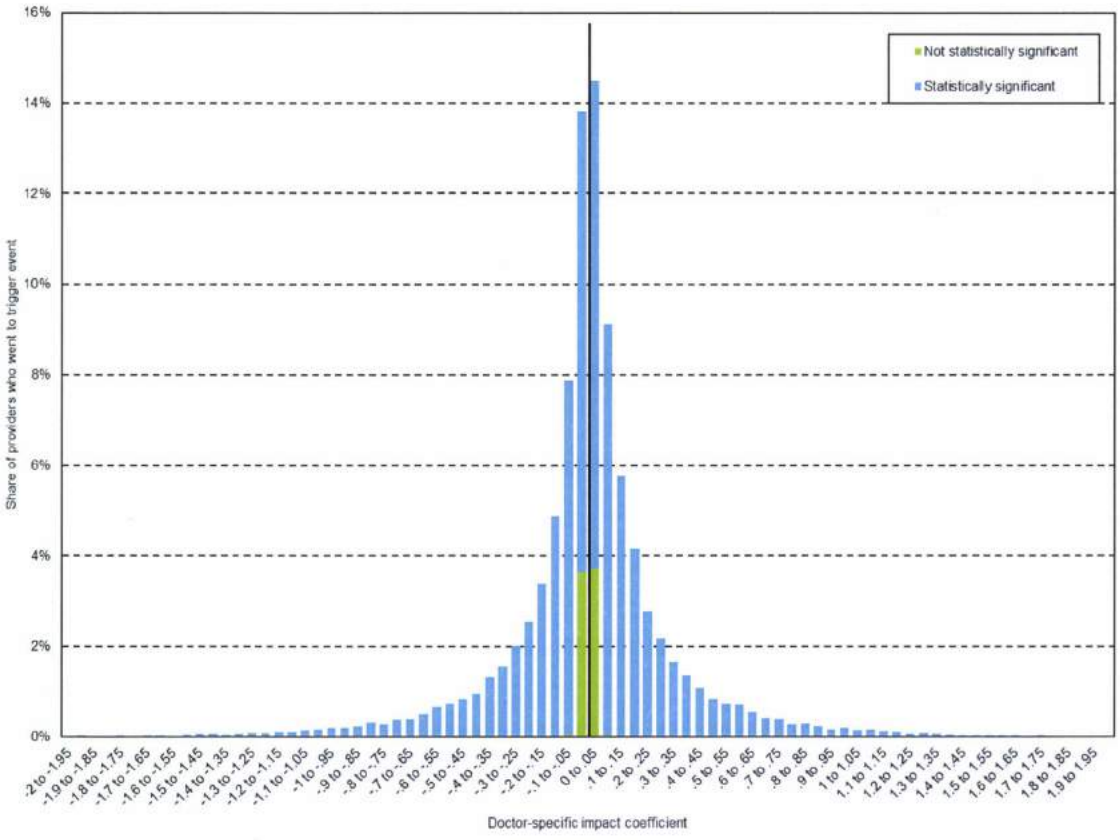
Source: Concerto event data; IMS Health.

Figure 59: Distribution of doctor-specific impact coefficients for Tekturna HCT with statistical significance



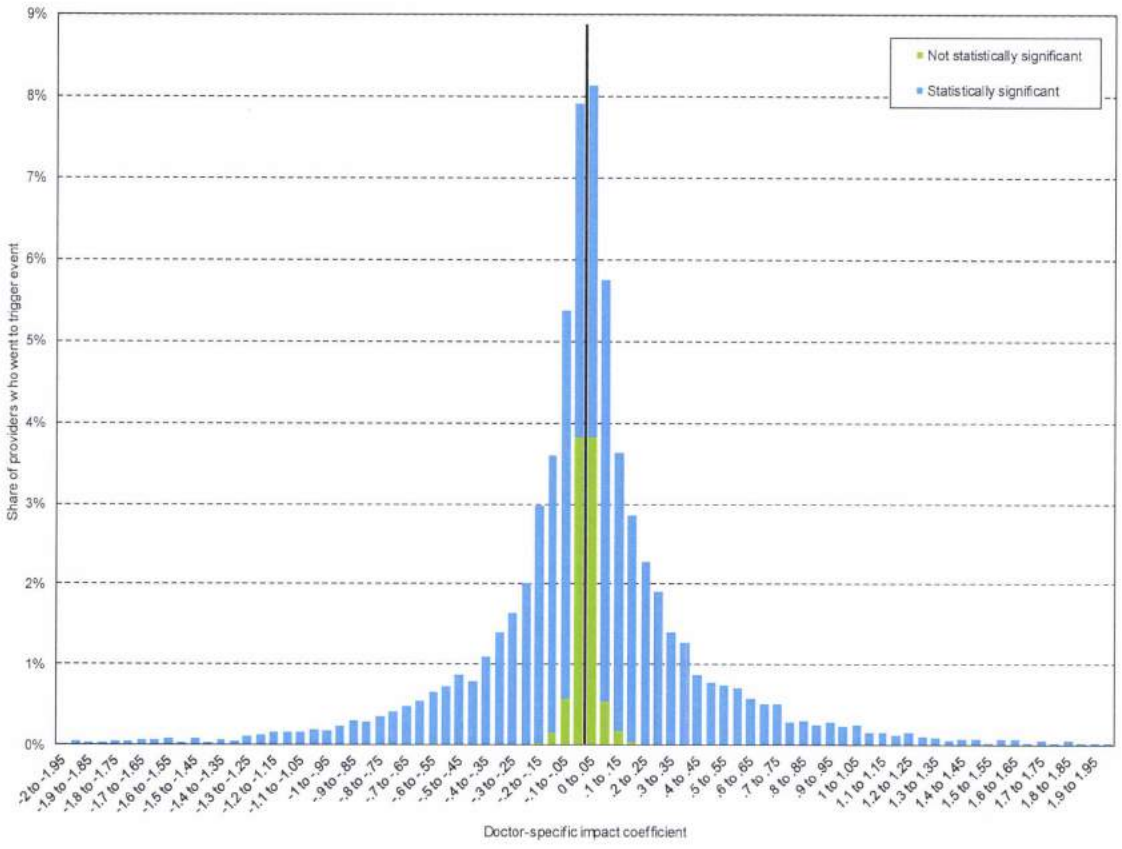
Source: Concerto event data; IMS Health.

Figure 60: Distribution of doctor-specific impact coefficients for Lotrel with statistical significance



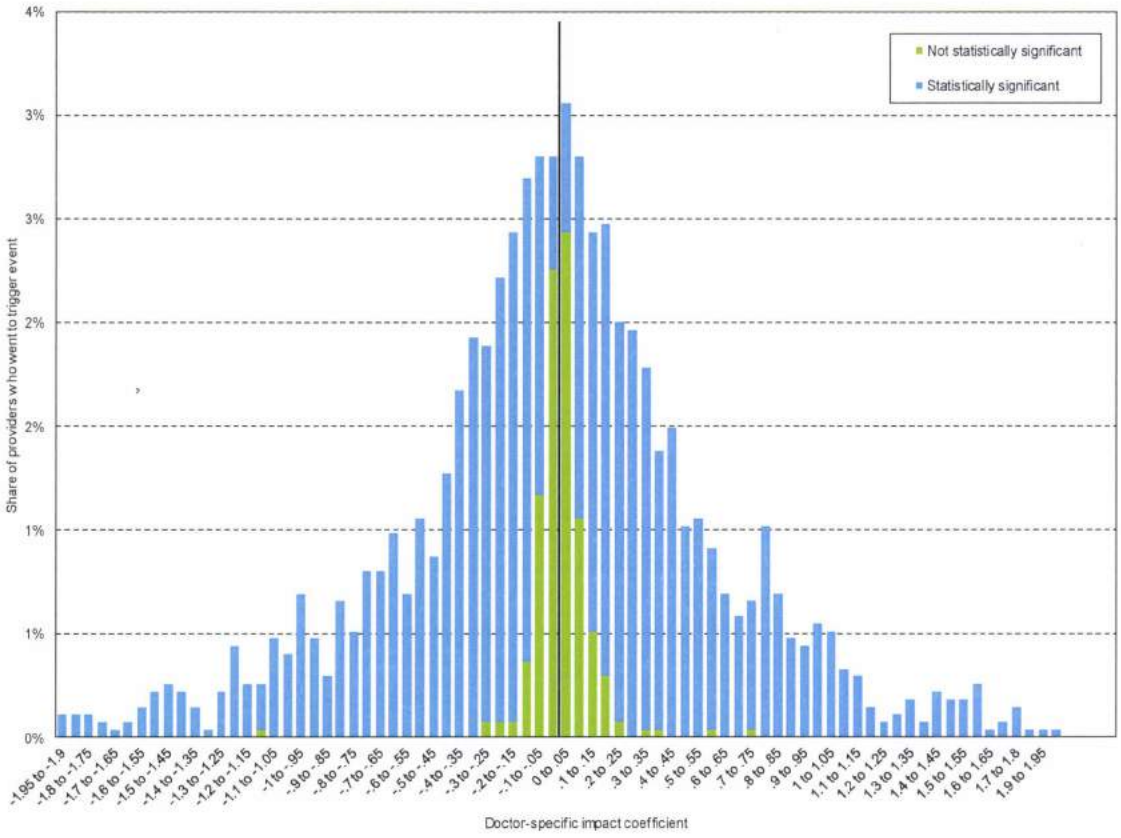
Source: Concerto event data; IMS Health.

Figure 61: Distribution of doctor-specific impact coefficients for Starlix with statistical significance



Source: Concerto event data; IMS Health.

Figure 62: Distribution of doctor-specific impact coefficients for Valturna with statistical significance



Source: Concerto event data; IMS Health.

Appendix H. Doctors, trigger events, and sales representatives associated with event adjustments

Figure 63: Summary of trigger events, sales representatives, and doctors after correcting some flaws in his model and data inputs

Adjustment to challenged claims/events	Trigger events	Sales representatives	Doctors	
			Prof. McFadden's model	Prof. McFadden's model correcting for some confounding factors, serial correlation, and doctor-specific impact
Baseline	182,375	8,081	50,977	31,965
Remove MM claims and additional lunch-and-learns (L&Ls) and correct meal spending	146,203	7,834	41,492	25,355
Remove MM claims, L&Ls, and pre-2010 Diovan, Exforge, and Tekturna (DET) events and correct meal spending	24,333	2,989	14,314	9,575
Remove MM claims, L&Ls, pre-2010 DET events, and pre-2010 DET+HCT events and prescriptions and correct meal spending	23,503	2,747	14,110	9,430

Source: Concerto event data; IMS Health; McFadden Report; Novartis details data; Novartis samples data.